A Dissertation on

"A COMPARATIVE STUDY ON VARIOUS MODALITIES OF VARICOSE VEINS TREATMENT AT RAJIV GANDHI GOVT GENERAL HOSPITAL FROM JUNE TO SEPT.2015 A PROSPECTIVE STUDY"

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DISSERTATION SUBMITTED FOR THE DEGREE OF MASTER OF SURGERY

BRANCH-1 (GENERAL SURGERY) AT MADRAS MEDICAL COLLEGE, CHENNAI.



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CERTIFICATE

This is to certify that, the dissertation entitled "A COMPARATIVE STUDY ON VARIOUS MODALITIES OF VARICOSE VEINS TREATMENT AT RAJIV GANDHI GOVT. GENERAL HOSPITAL FROM JUNE TO SEPT. 2015 – A PROSPECTIVE STUDY" is the bonafide work done by DR.MOHAMED NOOHU BARIZ S.A.K. during his M.S. General Surgery course 2013 – 2016, done under my supervision and is submitted in partial fulfillment of the requirement for the M.S. (BRANCH 1) – GENERAL SURGERY of the Tamilnadu Dr. M.G.R. Medical University, April 2016 examination.

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DECLARATION

I, Dr. MOHAMED NOOHU BARIZ S.A.K., certainly declare that this dissertation titled "A COMPARATIVE STUDY ON VARIOUS MODALITIES OF VARICOSE VEINS TREATMENT AT RAJIV GANDHI GOVT. GENERAL HOSPITAL FROM JUNE TO SEPT 2015 – A PROSPECTIVE STUDY" represents a genuine work of mine. The contributions of any supervisors to the research are consistent with normal supervisory practice and are acknowledged. I also affirm that this bonafide work or part of this work was not submitted by me or any others for any award, degree or diploma to any other university board, either in India or abroad. This is submitted to the Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulations for the award of Master of Surgery degree Branch 1 (General Surgery).

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Date:

Place:

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Dear Dr. Mohamed Noohu Bariz,

The Institutional Ethics Committee has considered your request and approved your study titled "A comparative study on various modalities of varicose veins treatment at Rajiv Gandhi Government General Hospital" No.15062015.

The following members of Ethics Committee were present in the meeting held on 09.06.2015 conducted at Madras Medical College, Chennai-3.

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE CHENNAI-600 003

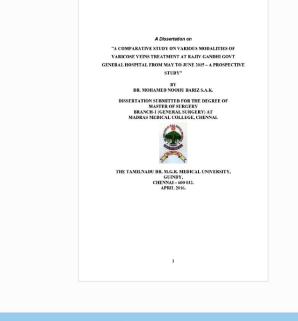
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INTRODUCTION

Varicose veins affect 10-20 percent of the population and about 2% have skin changes which may precede venous ulceration. Varicose veins recognized since biblical times. The use of compression therapy dates back to Roman times, soldiers using tight wraps to reduce the discomfort due to prolonged standing.

However, our modern understanding of varicose veins did not arise until the work of Brodie and Trendelenburg in the 1850s and 1890s

Trendelenburg was credited with introducing surgery for varicose veins, thus marking the beginning of modern vascular surgery for this problem.

Surgery is still the best and reliable therapeutic option for treatment of varicose veins. High ligation, stripping and excision/ligation of varicose veins is a procedure that was introduced at the turn of 19th to 20th century.

Reported rates of recurrence of the disease after treatment of superficial varicose veins range from 7-65 percent.Stripping of long saphenous vein only in the thigh reduces the incidence of nerve injury and reduces the incidence of recurrence by ensuring the avulsion of potential perforating veins.

Endovenous ablation has replaced stripping and ligation as the technique for elimination of saphenous vein reflux. One of the endovenous techniques is a radiofrequency-based procedure. Newer methods of delivery of radiofrequency were introduced in 2007. Endovenous procedures are far less invasive than surgery and have lower complication rates. The procedure is well tolerated by patients, and it produces good cosmetic results.

Therefore, it was intended to undertake a study to compare long saphenous vein stripping from groin to knee, high saphenofemoral junction ligation and radiofrequency ablation in the treatment of varicose veins with saphenofemoral incompetence.

AIM OF THE STUDY

- 1. To compare the effectiveness of each treatment
- 2. To compare the complications involved in various procedures

REVIEW OF LITERATURE

EPIDEMIOLOGY

The prevalence of varicose veins is around 5%- 30% in the adult population, but reports have ranged from less than 1% to greater than 70%. The prevalence is higher in developed, industrial countries than in underdeveloped countries.

Most studies found a greater prevalence of varicose veins in females, with an approximate twofold predominance, but this was not universal. In contrast, other studies, including the Edinburgh Vein Study, reported a greater prevalence of varicose veins in men than in women.

The apparent female predilection has been presumed to be due to the effect of pregnancy and possibly hormonal influences. Numerous other risk factors are associated with the development of varicose veins, including old age, family history, obesity and a standing occupation. Additional behavioral factors such as smoking, physical inactivity, and low-fiber diets also suggested to play a role.

ANATOMY

To determine the pathology, detail knowledge of venous anatomy is essential. After the location and type of venous incompetence have known, a treatment option can be planned. Venous drainage of the legs is the function of two parallel and connected systems, the deep and superficial systems.

Superficial Venous System

The superficial veins of lower extremity form a network that connects the superficial dorsal veins of foot and deep plantar veins. The dorsal venous arch, into which empty the dorsal metatarsal veins, is continuous with the GSV medially and the SSV laterally.

The **great saphenous vein**, in close proximity to saphenous nerve, ascends anterior to medial malleolus, crosses and then medial to the knee. It ascends in superficial compartment and empties into the common femoral vein after entering the fossa ovalis.

Before entering into the common femoral vein, GSV receives medial and lateral accessory saphenous veins, as well as small tributaries from the inguinal region, pudendal region, and anterior abdominal wall

The posterior arch vein drains the area around medial malleolus and, as it ascends up the posterior medial aspect of the calf, it receives medial perforating veins, termed *Cockett's perforators*, before joining the great saphenous vein at or below the knee.

The **small saphenous vein** arises from dorsal venous arch at lateral aspect of the foot and ascends posterior to lateral malleolus, rising cephalad in the midposterior calf.

The small saphenous vein continues to ascend, penetrates the superficial fascia of the calf, and then terminates into the popliteal vein.

The exact entry of the small saphenous vein into the popliteal vein is variable. The sural nerve lies parallel to the small saphenous vein.

Perforating Venous System

Perforating veins connect superficial venous system to deep venous system by penetrating fascial layers of the lower extremity. These perforators run in a perpendicular fashion to the axial veins. Although the total number of perforator veins is variable, up to 100 have been documented.

The perforators enter at various points in the leg—the foot, medial and lateral calf, and mid and distal thigh. Some have been named **Cockett's perforators**, which connects posterior arch and posterior tibial veins, **Boyd's perforators**, which connects great saphenous and gastrocnemius veins, and **Hunterian and Dodd's perforators**, which connect the great saphenous and superficial femoral veins.

The valve system of perforators aids in preventing reflux from the deep to the superficial system, particularly during periods of standing and ambulation.

Normal Venous Histology and Function

The venous wall is composed of 3 layers, the intima, media, and adventitia. Vein walls have less smooth muscle and elastin than their arterial counterparts. The venous intima has an endothelial cell layer resting on a basement membrane. The media is composed of smooth muscle cells and elastin connective tissue. The adventitia of the venous wall contains adrenergic fibers, particularly in the cutaneous veins.

The histologic features of veins vary, depending on the caliber of veins. The venules, range from 0.1 to 1 mm and contain mostly smooth muscle cells, whereas the larger extremity veins contain relatively few smooth muscle cells. These larger caliber veins have less contractile capacity in comparison to thicker walled great saphenous vein. The venous valves prevent retrograde flow; their failure or valvular incompetence that leads to reflux and its associated symptoms. Venous valves are most prevalent in the distal lower extremity, whereas as one proceeds proximally, the number of valves decreases to the point that no valves are present in the superior vena cava and inferior vena cava.

Most of the capacitance of the vascular tree is in the venous system. Because veins do not have significant amounts of elastin, veins can withstand large volume shifts with comparatively small changes in pressure.

A vein has a normal elliptical configuration until the limit of its capacitance is reached, at which point the vein assumes a round configuration.

The calf muscles augment venous return by functioning as a pump. The return of blood to heart from the lower extremity is facilitated by muscle pump function of the calf, a mechanism whereby the calf muscle, functioning as a bellows during exercise, compresses the gastrocnemius and soleal sinuses and propels the blood towards the heart.

During calf muscle contraction, the venous pressure of the foot and ankle drop dramatically. The pressures developing in the muscle compartments during exercise range from 150 to 200 mm Hg and, when there is failure of perforating veins, these high pressures are transmitted to the superficial system.

VENOUS INSUFFICIENCY

There are three categories of venous insufficiency-congenital, primary, and secondary Congenital venous insufficiency is comprised of anatomic variants that are present at birth. Examples include venous ectasias, absence of venous valves, and syndromes such as Klippel-Trenaunay syndrome.

Primary venous insufficiency is an acquired idiopathic entity. This is the largest clinical category and represents most of the superficial venous insufficiency encountered in the office.

Secondary venous insufficiency arises from a post-thrombotic or obstructive state and is caused by a deep vein thrombus or primary chronic obstructive process.

Primary Venous Insufficiency

There are three main anatomic categories of primary venous insufficiency-**telangiectasias, reticular veins, and varicose veins**. Telangiectasias, reticular varicosities, and varicose veins are similar but exhibit distinct variations in caliber.

Telangiectasias are small intradermal venules that are too diminutive to demonstrate reflux. Reticular veins are vein branches that enter the tributaries of the main axial, perforating, or deep veins.

The axial veins, the great or small saphenous veins, represent the largest caliber veins of the superficial venous system.

Pathology

The precise pathology of venous insufficiency has yet to be elucidated. Here we describe some of the areas in which research has started to reveal its multifactorial pathogenesis.

Mechanical Abnormalities

Anatomic differences in location of the superficial veins of the lower extremities may contribute to pathogenesis. Primary venous insufficiency may involve both axial veins (great and small saphenouss), either, or neither.

Perforating veins may be the sole source of venous pathology, perhaps because the GSV is supported by a well-developed medial fibromuscular layer and fibrous connective tissue that bind it to the deep fascia.

In contrast, tributaries to SSV are less supported in the subcutaneous fat and are superficial to the membranous layer of superficial fascia. These tributaries also contain less muscle mass in their walls. Thus, these veins, may become selectively varicose.

When these fundamental anatomic peculiarities are recognized, the intrinsic competence or incompetence of the valve system becomes important. For example, failure of a valve protecting a tributary vein from the pressures of the small saphenous vein allows a cluster of varicosities to develop.

Furthermore, communicating veins connecting the deep with the superficial compartment may have valve failure.

Venous Hypertension

Studies have shown that there are two sources of venous hypertension. The first is gravitational, which is a result of venous blood coursing in a distal direction down linear axial venous segments. This is referred to as hydrostatic pressure and is the weight of the blood column from the right atrium. The highest pressure generated by this mechanism

is evident at the ankle and foot, where measurements are expressed in centimeters of water or millimetres of mercury.

The second source of venous hypertension is dynamic. It is the force of muscular contraction, usually contained within the compartments of the leg.

If a perforating vein fails, high pressures (range, 150 to 200 mm Hg) developed within the muscular compartments during exercise are transmitted directly to the superficial venous system. Here, the sudden pressure transmitted causes dilation and lengthening of the superficial veins. Progressive distal valvular incompetence may occur.

If proximal valves such as the saphenofemoral valve become incompetent, systolic muscular contraction is supplemented by the weight of the static column of blood from the heart. Furthermore, this static column becomes a barrier.

Blood flowing proximally through the femoral vein spills into the saphenous vein and flows distally. As it refluxes distally through progressively incompetent valves, it is returned through perforating veins to the deep veins. Here, it is conveyed once again to the femoral veins, only to be recycled distally.

<u>Cellular Abnormalities</u>

Changes also occur at cellular level. Angioscopic observation demonstrates monocytic and macrophage infiltration in those vein valves affected by venous insufficiency.

In regions of chronic advanced venous insufficiency, such as advanced lipodermatosclerosis, capillary proliferation is seen and extensive capillary permeability occurs as a result of widening of interendothelial cell pores. Transcapillary leakage of osmotically active particles occurs, mainly of fibrinogen. In chronic venous insufficiency, venous fibrinolytic capacity is diminished and the extravascular fibrin remains to prevent the normal exchange of oxygen and nutrients in the surrounding cells. However, little proof exists for an actual abnormality in the delivery of oxygen to the tissues.

Molecular Abnormalities

On a molecular level, several abnormalities identified in extremities that manifest venous hypertension. Varicose veins demonstrate less amounts of elastin and collagen, suggesting a contributing role toward venous pathology.

Risk Factors

Risk factors for the development of varicose veins include advancng age, female gender, heredity, and history of trauma to the extremity. Venous function is undoubtedly influenced by hormonal changes.

Symptoms

Venous valvular dysfunction causes venous hypertension and, as such, patients' symptoms are attributed to excess venous pooling. The patient with symptomatic varicose veins commonly reports heaviness, discomfort, and extremity fatigue.

The pain is characteristically dull, does not usually occur during recumbency or early in morning, and is exacerbated in afternoon, especially after periods of prolonged standing. Swelling is commonly described. The discomforts of aching, heaviness, and/or fatigue are usually relieved by leg elevation or elastic support.

Cutaneous burning, termed *venous neuropathy*, can also occur in patients with advanced venous insufficiency. **Pruritus** occurs from excess hemosiderin deposition and tends to be located at the distal calf or in areas of phlebitic varicose branch segments.



Physical Examination

A comprehensive examination includes assessment of the arterial circulation. Briefly, palpation of the femoral, popliteal, dorsalis pedis, and posterior tibialis pulses is performed.

Auscultation of pulse flow is indicated when a thrill or widened pulse is appreciated. Demonstration of decreased hair, dependent rubor, pallor on

elevation, and tissue loss are all indicative of advanced arterial ischemia.

The venous examination includes assessment of the patient in the standing and supine positions. Standing increases venous hypertension and dilates veins, thereby facilitating examination.

Patients with superficial axial incompetence commonly exhibit palpable great saphenous veins. Palpable cords may be present. Visual inspection is critical. Signs of advanced venous insufficiency include hyperpigmentation in the gaiter distribution, secondary to hemosiderin deposition, and lipodermatosclerosis. Lipodermatosclerosis develops over time, due to prolonged ambulatory venous hypertension and chronic inflammation.

Physical examination findings that reflect lipodermatosclerosis are: brawny edema of the distal calf, "champagne bottle leg," fibrotic, hypertrophic skin, and hyperpigmentation. Advanced lipodermatosclerosis may involve fibrosis of the Achilles tendon, impairing motor function of the extremity.

Corona phlebectica is a term used to describe an accumulation of tiny telangiectasias or venous flare, usually located at the medial malleolus. Venous stasis ulcers exhibit pathognomonic features that distinguish them from their arterial or neuropathic counterparts. Venous ulcers are not generally painful and appear at the malleolus, not in the mid to distal foot.



Venous ulceration located proximal to the medial malleolus

Lack of arterial pulses in patients with a venous ulcer is unusual. Venous stasis dermatitis is visualized at the distal ankle and can mimic eczema or dermatitis of another cause. It is this important attention to supporting features of the physical examination and history, as well as confirmation with duplex reflux examination, that will distinguish advanced venous stasis disease from dermatologic conditions.

Diagnostic Evaluation of Venous Dysfunction

The Perthes test for deep venous occlusion and Brodie-Trendelenburg test of axial reflux have been replaced by in-office use of the continuous wave, hand-held Doppler instrument supplemented by duplex evaluation.



The hand-held Doppler can confirm an impression of saphenous reflux, which in turn dictates the operative procedure to be performed in a given patient. A common misconception is the belief that the Doppler instrument is used to locate perforating veins. Instead, it is used in specific locations to determine incompetent valves—for example, the hand-held, continuous wave, 8-MHz flow detector placed over the greater and lesser saphenous veins near their terminations. With distal augmentation of flow and release, normal deep breathing, and performance of a Valsalva maneuver, valve reflux is accurately identified.

Duplex technology more precisely defines which veins are refluxing by imaging the superficial and deep veins. The duplex examination is commonly done with the patient supine, but this yields an erroneous evaluation of reflux. In the supine position, even when no flow

is present, the valves remain open. Valve closure requires a reversal of flow with a pressure gradient that is higher proximally than distally. Thus, the duplex examination needs to be done with the patient standing or in the markedly trunk-elevated position. Imaging is obtained with a 7.5- or 10-MHz probe; the pulsed Doppler consists of a 3.0-MHz probe. The patient stands, with the probe placed longitudinally on the groin. After imaging, sample volumes can be obtained from the femoral and saphenous veins. This flow can be observed during quiet respiration or distal augmentation. Sudden release of augmentation allows the assessment of valvular competence. The small saphenous vein and popliteal veins are similarly examined. Reflux times of 3 seconds or longer is considered significant.

Perforator veins can be visualized with duplex examination. Demonstration of duplex images of to and fro flow, with the presence of dilated segments, constitutes findings compatible with a refluxing perforator. Additionally, Doppler studies can provide the clinician with information about the deep system. Widespread use of duplex scanning has allowed a comparison of findings between standard clinical examinations and duplex Doppler studies.

Phlebography and Venography

Phlebography is unnecessary in diagnosis and treatment of primary venous insufficiency. In cases of secondary chronic venous insufficiency,

phlebography has specific usefulness. Ascending phlebography is performed via injection of contrast into a superficial pedal vein after a tourniquet is applied at the ankle to prevent flow into the superficial venous system. Observation of flow indicates defines anatomy and regions of thrombus or obstruction. Therefore, ascending phlebology differentiates primary from secondary venous insufficiency.

Descending phlebography is performed with retrograde injection of contrast into deep venous system at groin or popliteal fossa. This diagnostic modality identifies specific valvular incompetence suspected on B mode scanning and clinical examination. These studies are only performed as preoperative adjuncts when deep venous reconstruction is being planned.

Magnetic Resonance Venous Imaging

Magnetic resonance venous imaging is a diagnostic imaging modality reserved for evaluation of abdominal and pelvic venous vasculature. MRVI, unlike venography, is noninvasive and does not require IV contrast. Furthermore, studies have documented similar rates of specificity and sensitivity when compared with venography. MRVI is used for the evaluation of congenital malformations and identification of chronic and acute venous thrombi.

CLASSIFICATION SYSTEMS

American Venous Forum devised the CEAP classification system, a scoring system that stratifies venous disease based on *clinical* **presentation**, *etiology*, *anatomy*, *and pathophysiology*.

A revised CEAP was introduced which included a venous disability score to document a patient's ability to perform activities of daily living.

Although the CEAP classification is a valuable tool to grade venous disease, assessment of outcomes following intervention cannot be realized. As a result, two additional scoring systems, the venous clinical severity scoring system (VCSS) and venous segmental disease score (VSDS), enhance the CEAP score with the increased ability to plot outcome. These three classification modalities provide clinicians with invaluable tools to study treatment outcomes.

Classification of Chronic Lower Extremity Venous Disease

C Clinical signs (grade0-6), supplemented by "A" for asymptomatic and "S" for symptomatic presentation

E by Etiology - congenital, primary, secondary

A Anatomic distribution - superficial, deep, or perforator, alone or in combination

P Pathophysiologic dysfunction - *r*eflux or *o*bstruction, alone or in combination.

Clinical Classification (C0-6)

Any limb with possible chronic venous disease is first placed into one of seven clinical classes (C0-6), according to the objective signs of disease.

Clinical Classification of Chronic Lower Extremity Venous Disease*

CLASS FEATURES

0 No visible or palpable signs of venous disease
1 Telangiectasia, reticular veins, malleolar flare
2 Varicose veins
3 Edema without skin changes
4 Skin changes ascribed to venous disease (e.g., pigmentation, venous eczema, lipodermatosclerosis)
5 Skin changes as defined above with healed ulceration
6 Skin changes as defined above with active ulceration

Limbs in higher categories have more severe signs of chronic venous disease and may have some or all of the findings defining a less severe clinical category. Each limb is further characterized as asymptomatic (A)—for example, C0-6,A—or symptomatic (S)—for example, C0-6,S. Symptoms that may be associated with telangiectatic, reticular, or varicose veins include lower extremity aching, pain, and skin irritation. Therapy may alter the clinical category of chronic venous disease. Limbs should therefore be reclassified after any form of medical or surgical treatment.

Classification by Cause

Venous dysfunction may be **congenital**, **primary**, **or secondary**. These categories are mutually exclusive. Congenital venous disorders are present at birth but may not be recognized until later. The method of diagnosis of congenital abnormalities must be described. Primary venous dysfunction is defined as venous dysfunction of unknown cause but not of congenital origin. Secondary venous dysfunction denotes an acquired condition resulting in chronic venous disease - for example, deep venous thrombosis.

Classification by Cause of Chronic Lower Extremity Venous Disease

Congenital (EC) Cause of the chronic venous disease present since birth.

Primary (EP) Chronic venous disease of undetermined cause.

Secondary (ES) Chronic venous disease with an associated known cause (e.g., post-thrombotic, post-traumatic, other).

Anatomic Classification (AS, AD, or AP)

The anatomic site of the venous disease should be described as superficial (AS), deep (AD), or perforating (AP) vein(s). One, two, or three systems may be involved in any combination. For reports requiring greater detail, the involvement of the superficial, deep, and perforating veins may be localized by use of the anatomic segments.

Segmental Localization of Chronic Lower Extremity Venous Disease

SEGMENT NO. VEIN(s)

Superficial Veins (AS1-5)

1 Telangiectasia/reticular veins

Greater (long) saphenous vein

- 2 Above knee
- 3 Below knee
- 4 Lesser (short) saphenous vein
- 5 Nonsaphenous

Deep Veins (AD6-16)

6 Inferior vena cava

ILIAC

- 7 Common
- 8 Internal
- 9 External
- 10 Pelvic: gonadal, broad ligament

FEMORAL

11 Common

Treatment of Superficial Venous Insufficiency

Nonoperative Management as noted, symptoms of primary venous insufficiency are manifestations of valvular incompetence. Therefore, the objective of conservative management is to improve the symptoms caused by venous hypertension. The first measure is external compression using elastic hose, 20 to 30 mm Hg, to be worn during the daytime hours. Although the exact mechanism whereby compression is of benefit is not entirely known, a number of physiologic alterations have been observed with compression. These include reduction in ambulatory venous pressure, improvement in skin microcirculation, and increase in subcutaneous pressure. Patients are instructed to wear the bandage during the day only, but to put the stockings on as soon as the day begins; swelling with standing will make stocking placement difficult. Care must be taken with patients who have concomitant arterial insufficiency because the compression stockings may exacerbate arterial outflow to the foot. Therefore, these patients require less compression-in some cases no compression whatsoever - depending on the severity of the arterial disease.

The second part of conservative therapy is to practice lower extremity elevation for two brief periods during the day, instructing the patient that the feet must be above the level of the heart. With good compliance, these measures may ameliorate symptoms so that patients may not require further intervention.

Third, patients are encouraged to participate in activities that activate the calf musculovenous pump, thereby decreasing ambulatory venous hypertension. These activities include frequent ambulation and exercise. Patients who exhibit venous stasis ulceration will require local wound care. A triple-layer compression dressing, with zinc oxide paste gauze wrap in contact with the skin, is used commonly, from the base of the toes to the anterior tibial tubercle with snug graded compression. This is an example of what is generally known as an *Unna boot*.

Indications for interventional treatment are symptoms refractory to conservative therapy, recurrent superficial thrombophlebitis, variceal bleeding, and venous stasis ulceration.

SURGICAL TECHNIQUES

Surgery for varicose veins should be individualized according to patient's preop evaluation. A combination of ligation, axial stripping, and stab phlebectomy may be applied as needed to the GSV, SSV, tributary veins, and perforating veins.

After preoperative evaluation and elucidation of the necessary scope of surgery, a decision will be made regarding the appropriate method of anesthesia and site of service. Preoperative marking of the patient in the standing position with an indelible marker is important in any case in which stab phlebectomy or direct perforator ligation is contemplated. Such marking is essential because visualization of varicose tributaries may be impossible once the patient is prepared and the leg elevated. Patients are to be shaved immediately preoperatively with a clipper and the leg cleansed with an appropriate surgical preparation.

HIGH LIGATION OF THE GREAT SAPHENOUS VEIN

The GSV is most easily approached through an oblique incision 1 cm below and parallel to the groin crease. This location provides the best cosmetic results and the most reliable access to the saphenofemoral junction. Some surgeons, however, recommend an incision right in the groin crease. The incision should start over the palpable femoral artery and extend medially to balance the better cosmesis of limited incisions with the necessity to ensure appropriate visualization of the saphenofemoral junction and its tributaries.

Preoperative DUS-guided marking of the saphenofemoral junction further improves the precision of incision placement and allows minimal incision size and subcutaneous dissection. As the subcutaneous tissue is split, the main trunk of the GSV is identified. A self-retaining retractor is helpful, and the plane over the saphenous vein is extended toward the saphenofemoral junction. This anterior plane is generally free of encumbrances and allows exposure to the junction. Each of the tributaries is divided and ligated because the SFJ needs to be clearly identified. Failure to clearly define the saphenofemoral junction has resulted in disastrous injuries to the femoral vein or artery.

There are six main tributaries joining the GSV near its termination. However, the number and position of these tributaries highly varies, and therefore it is necessary to dissect the femoral vein 2 cm above and below the confluence to be sure that no additional tributaries join the femoral vein directly. Lateral and medial accessory saphenous veins may enter the main trunk between 2 and 20 cm below the confluence.

When stripping is planned, these distal tributaries are avulsed, but if ligation alone is planned, the dissection should be extended caudad for approximately 10 cm to ensure division of these hidden tributaries. High ligation of the GSV is performed close to the femoral vein. Double ligation performed on a proximal stump with the second ligation being a suture ligature. Care should be taken to avoid narrowing the femoral vein. Equally important is to avoid leaving a long stump with a risk for thrombus formation and potential embolism. If high ligation alone is to be performed, one should resect the segment of GSV exposed in the surgical field, generally 5 to 10 cm in length.

The incision is closed in layers by approximating the subcutaneous tissue with absorbable suture and the skin with absorbable subcuticular or interrupted nylon suture.

Great Saphenous Vein Stripping

GSV stripping is the central component of classic operation for varicose veins. Recurrence rates are markedly reduced when the GSV is stripped as opposed to performing high ligation alone, therefore high ligation is usually performed in conjunction with treatment of the GSV. During preoperative marking for L&S of the GSV, the surgeon should review the extent and distribution of reflux disease in the saphenous system. The GSV in the thigh is incompetent in only about two thirds of patients undergoing surgery for symptomatic varicose veins. In addition, unless the caudal below-knee saphenous vein is obviously incompetent and varicose, there is no need to remove it.

After flush ligation is performed, a transverse venotomy is created and a stripper is passed distally. In most cases the presence of reflux allows easy passage of the stripper to the level of the knee. A second small incision is made over the palpable stripper near the knee. The caudal incision is made transversely and the subcutaneous tissues dissected to allow recovery of the saphenous vein. This top-down passage of the stripper not only facilitates identification of the saphenous vein at the knee and allows a small lower incision to be made but also avoids the potential for the stripper passed from below to enter the femoral vein through a thigh perforator and cause the femoral vein to be mistaken for the saphenous vein. The GSV should be stripped in a downward direction, which results in improved avulsion of tributaries and diminished injuries to the saphenous nerve. To avulse the vein with the endoluminal stripper one needs to affix the catheter to the most cephalic portion of the vein. This may be accomplished by attaching the classic stripper head to the top of the disposable stripper after first placing a silk ligature around the vein and the stripper just below the head. Using the smallest head size minimizes tissue injury and bruising, whereas a larger head size will improve one's chance of recovering the entire vein and the tributary segments.

A long trailing silk suture is initially attached at the stripper head and drawn through the tunnel with the vein. After all the tributaries are avulsed and the caudal GSV divided and ligated, the vein is drawn back up to the groin incision, thereby minimizing the distal incision.

Although many variations of this technique have been described, the most common alternative approach involves invagination of the GSV into itself. This technique may be performed with a disposable plastic Codman Vein Stripper without attaching a stripper head but instead intussuscepting the vein. Alternatively, a reusable metal cannula may be used in a similar fashion. This technique minimizes the diameter of tunnel created by vein removal in an effort to diminish local trauma to soft tissues and nerves. However, the saphenous vein is susceptible to tearing at the sites of tributary confluence and thus could result in incomplete stripping of the target vein. Consequently, when the vein is removed, it should be unfurled and compared with the planned treatment length. When the vein is torn during stripping, the caudal end typically remains in place at the lower incision. In this case, if a trailing heavy silk suture has been affixed to the stripper, a second inversion technique could be performed in the opposite direction

Adjunctive Considerations for Stripping Procedures

Saphenous vein stripping is commonly perceived as a painful and morbid procedure by patients and referring physicians alike. The memory of large incisions, extensive bruising, significant pain, and prolonged disability from antiquated techniques is a major concern of patients and referring physicians. These undesirable effects can be significantly ameliorated by using relatively simple adjunctive techniques.

Ultrasound Guidance

DUS used to preoperatively mark the saphenofemoral or saphenopopliteal junction. It allows precise placement of the skin incision and permits very small incisions with limited subcutaneous dissection.

Tumescent Anesthesia

The GSV in thigh lies within a fascial envelope, which allows modest infusion of tumescent anesthesia (200 to 500 mL) to fully surround the saphenous vein. We use a combination of 40 mL of 1%

lidocaine with epinephrine, 10 mL of sodium bicarbonate, and 450 mL of normal saline. This technique provides excellent anesthesia and allows vein stripping to be performed under straight local anesthesia in an office setting.

Minimization of Accumulation of Blood in the Stripping Tunnel

If blood is left in place in the stripping tunnel, a firm palpable cord sometimes called pseudothrombophlebitis results. This will eventually reabsorb but contributes to the significant early discomfort.

In addition to the use of tumescent anesthesia, we recommend that stripping be performed as the last step of the procedure if concurrent tributary varices or perforator disease is to be addressed at the same setting. In this way the leg can be immediately wrapped in a compressive dressing and elevated after the vein stripping is performed.

Leg Elevation before and during Stripping

Elevation of the leg reduces the venous bleeding and ecchymosis associated with stripping. The leg should be elevated before the actual stripping procedure is performed. Postoperatively, the patient should ambulate as soon as possible.

<u>SURGERY ON THE SMALL SAPHENOUS VEIN AND VEINS OF</u> THE POPLITEAL FOSSA

SSV disease is often neglected by surgeons and, when addressed, is frequently incompletely treated. This problem may be explained by the following factors:

- the paucity of studies emphasizing a significant contributory role of SSV
- (2) the lower proportion of limbs with SSV reflux than with GSV incompetence
- (3) technical considerations, such as the need to reposition the patient if both GSV surgery and SSV surgery are being performed in the same treatment session
- (4) the intimate and variable neurovascular relationships of the SSV, which can present significant potential for morbidity.

Although nearly 90% of surgeons carried out preoperative duplex imaging, only 50% added preoperative skin marking of the saphenopopliteal junction. In an effort to avoid damage to neurovascular structures and also DVT, few surgeons (10%) exposed the popliteal vein during this procedure, which would make treatment of gastrocnemius or popliteal area veins difficult.

An understanding of the relationship of the SSV to other veins of the popliteal fossa-the gastrocnemius veins, the intersaphenous vein, and popliteal area veins-is important to achieve optimal results with SSV surgery. If these veins are ignored, they can be a factor in persistence of reflux. These veins can be attacked directly only by open surgery and not by EVA or forms of sclerotherapy, particularly when these veins directly enter the popliteal vein.

Operative Technique

After induction of general, regional, or local anesthesia, patients are positioned prone with care taken to pad bony areas. To provide laxity of neurovascular structures in the popliteal fossa, the affected limb is slightly flexed at knee with a rolled towel placed under the ankle.

Preoperative marking by DUS allows a small skin incision to be made just distal to previously marked saphenopopliteal junction. The length of the transverse incision is dictated by the thickness of the subcutaneous tissue.

The fascia is opened along the line of the skin incision and the SSV identified. The SSV is traced distally to its position between the fascia and calf muscles. Because of the effects of sustained venous hypertension, the SSV can resemble an artery (popliteal), so continuous wave Doppler scrutiny of the vessel may be used on occasion to provide the surgeon with assurance that the structure is indeed venous in nature. The SSV is then divided between two right-angle clamps.

Care should be taken to dissect in the perivenous plane, and any nerve structure-usually sural-is carefully dissected from the SSV. Gentle retraction is used to avoid injury to the tibial nerve and to visualize the saphenopopliteal junction. However, if DUS identifies reflux in the gastrocnemius or popliteal area veins, the exposure is extended and the target veins ligated. The stump of the SSV is ligated with a 3-0 monofilament transfixion suture. If present, the common trunk of the SSV with either the gastrocnemius or intersaphenous veins is ligated proximally just above the popliteal vein, and the two veins in turn are also ligated.

The SSV is ligated distally with 3-0 monofilament suture. The popliteal wound is then irrigated and closed in layers with particular attention paid to approximating the fascia to avoid unsightly hernias. The short skin incision is approximated with running 5-0 subcuticular suture. Particular attention is paid to ligate any incompetent gastrocnemius perforating veins that connect with the SSV branches.

Excision of Local Varicosities (Ambulatory Phlebectomy)

By removing the source of axial reflux, flush L&S of the GSV, SSV, or both are responsible for the greatest hemodynamic benefit in most vein operations. However, the remaining superficial varicosities, if left uninterrupted, will drain via alternative pathways and may remain both symptomatic and cosmetically displeasing to patients. In the past, these varices were dealt with by making several large incisions, and dramatic transverse scars were left in many cases. Refinements in technique have resulted in improved cosmetic results with effective elimination of tributary varices through small (1 to 3 mm) stab incisions. Effective use of these minimally invasive techniques requires planning, experience, and patience. It is common for procedures to require in excess of 20 phlebectomies, which can be time-consuming. Preoperative marking is very important in ambulatory phlebectomy. These target veins are often difficult to see when the patient is reclining.

Phlebectomy is best performed on a horizontal plane, and because many patients are treated under a local anesthetic, it is often possible to have them rotate their extremity during the procedure to maximize exposure.

ENDOVENOUS THERMAL ABLATION

The evolution of minimally invasive techniques for the treatment of GSV reflux has culminated in the development of EVA. Under ultrasound guidance the saphenous vein is percutaneously accessed and the catheter advanced cephalad toward the saphenofemoral junction. Tumescent anesthesia and thermal energy are used in concert to provide an effective means of eliminating GSV reflux.

RESULTS

For a century L&S has been the "gold standard" for treatment of GSV incompetence and tributary avulsion for residual varicose veins. The preponderance of data advocating a surgical approach to varicose veins is derived from clinical reports of L&S. The role of L&S has diminished greatly with the advent of EVA by either laser or radiofrequency methods, and sclerotherapy has replaced tributary avulsion in many cases.

Results of Surgery on the GSV versus Conservative Treatment

The ESCHAR (Effect of Surgery and Compression on Healing And Recurrence) trial was the first large prospective randomized trial to address this fundamental question. Patients with severe sequelae of CVI (C5 to C6) and superficial or mixed deep and superficial venous insufficiency were randomized to medical therapy (elevation, compression, and exercise) either with or without surgical treatment of superficial venous reflux. Although no difference was found in rates of healing, there was a dramatic reduction in ulcer recurrence (12% versus 28% at 12 months; P < .001). This study has been criticized for using class II rather than class III stockings. However, it should be noted that both groups received the same compression garments and that in practice compliance drops off as the degree of compression is increased.

Michaels and colleagues recently carried out an RCT that examined the impact of superficial venous surgery on quality of life in 246 patients with uncomplicated varicose veins who were randomized to compression and lifestyle changes versus surgery with L&S of refluxing segments and multiple phlebectomies.

The surgical group showed significant improvement in qualityadjusted life years over the group treated by compression. Qualityadjusted life years as assessed by SF-36 were improved by 0.083 over the medically treated group and by 0.13 as assessed by the EQ-5D. In addition, the surgical group demonstrated significant anatomic and symptomatic relief. These large RCTs provide a grade A recommendation for surgery in addition to conservative treatment in patients with varicose veins caused by GSV reflux.

<u>Comparison of Results of Endovenous Ablation versus Ligation and</u> <u>Stripping of the Great Saphenous Vein</u>

Our review of the literature identified seven RCTs in which EVA was compared with L&S. Three of these studies compared laser treatment with L&S, whereas two compared radiofrequency ablation with L&S. These later two studies published subsequent follow-up data as two additional papers. The studies were of modest size, with 28 to 137 limbs being treated. Many of the RCTs were lacking some elements of proper study design: a prior calculation of sample size, comparability of baseline characteristics between groups, and intention-to-treat analysis.

Desirable outcome measures such as quality of life were used in six of the seven studies, whereas five of the seven RCTs provided a diseasespecific evaluative score so that preoperative values could be compared with postoperative values. Overall, there was an early postoperative advantage of EVA in quality of life, but by 1 month the disease-specific scores were comparable. "Soft" outcome measures such as return to normal activities or work and less postoperative pain also favored EVA.

Rasmussen, Perýlý, Darwood, and their colleagues found no difference between L&S and EVA in disease-specific scores by 1 month postoperatively. Four RCTs provided a postoperative quality of life assessment, but these measures were usually conducted late at an average of 1 month after the procedure. Two RCTs (Rasmussen and associates and Kalteis and colleagues showed no difference in quality of life measures, whereas two demonstrated an advantage for EVA (Rautio and associates and Lurie and colleagues). Morbidity is putatively less with EVA because the vein is ablated in place. L&S, however, involves stripping the vein with avulsion of branches and some tract bleeding, which can be mitigated but will never be completely eliminated. Certainly, if thrombophlebitis develops in the ablated GSV, the pain can be as severe as that with stripping. The use of postoperative analgesics is usual with L&S, in contrast to EVA.

We have observed that local tumescent anesthesia results in reduced pain and bruising with vein stripping and phlebectomy, as well as with EVA. Rasmussen and colleagues compared L&S and EVA in a randomized trial in which tumescent anesthesia was used in all patients. In this report, 121 patients (137 limbs) were randomized to high L&S with local anesthesia or endovenous laser treatment. Both groups had varicosities removed through miniphlebectomies and received perivenous tumescent solution and intravenous fentanyl. L&S was performed by the perforate-invaginate stripping technique. These treatments were found to be equally effective in eliminating GSV reflux, with no difference in time to resume normal activity or return to work. There was more pain and bruising in the L&S group but no change in pain medication. No difference was observed in the Venous Clinical Severity Score or in the Aberdeen score between the two groups at any time point. The bodily pain score component of the SF-36 was higher after L&S than after EVA 12 days postoperatively.

<u>Indications for Ligation and Stripping of the Great Saphenous Vein</u> in the Current Climate Favoring Endovenous Thermal Ablation

1. Superficial saphenous tributary. The most common indication for L&S of GSV is to treat a superficial tributary of the saphenous vein that is closely adherent to the skin. This vein can be an "extrafascial" continuation of the main GSV as a superficial branch or, alternatively, a separate anterior accessory saphenous vein or a truly duplicated GSV. The inability to create at least a 1-cm buffer zone between skin and vein with tumescent anesthesia during thermal ablation increases the risk for skin burns and is a clear contraindication to EVA. These patients more frequently undergo a stab phlebectomy of this venous segment rather than the classic L&S.

2. GSV dilatation or aneurysmal venous segments. Dilatation of the proximal GSV to greater than 2.5 to 3 cm or large aneurysmal venous segments along the course of the GSV are also an indication for L&S. Despite external compression, copious tumescent solution, and the use of high thermal energy by either laser or second-generation radiofrequency ablation, the proximal GSV may be difficult to ablate effectively and may be more prone to thrombotic complications.

3. Chronic thrombophlebitis. Synechial formation within the GSV as a sequela of superficial thrombophlebitis may prevent advancement of the

radiofrequency ablation catheter or laser sheath. This may occur even if a guide wire crosses the diseased segment. In this situation it is often possible to perform high L&S with the flexible Codman stripper or the relatively stiff wire PIN strippers. If this also fails, simple ligation plus segmental excision is performed. In addition, if the vein wall is noted to be markedly thickened on DUS, it will not constrict appropriately in response to thermal ablation and would be more effectively treated with L&S.

4. Excessive tortuosity (same considerations as in No. 3).

5. Acute superficial thrombosis. Acute superficial vein thrombosis with extension to saphenofemoral junction remains an indication for anticoagulation, GSV ligation, or both to prevent extension to the femoral vein. EVA is clearly contraindicated in any vein with acute thrombus.

In summary, L&S has decreased in popularity as a technique for treating GSV reflux because of the less invasive nature of EVA. However, for the previously stated reasons, L&S of the GSV remains a relevant procedure with a definite place in a modern venous practice.

ENDOVENOUS TREATMENT

BACKGROUND

The standard treatment of varicose veins for many years has been surgical L & S of the affected vein. Although outcomes have improved in recent years because of improved understanding of lower extremity venous anatomy, the failure rate with this approach is frequently reported to be between 20% and 30%. In addition, surgical ligation and stripping are invasive, usually requiring general anesthesia and several weeks' recovery before return to normal activities.

In response to need for a less invasive approach, numerous endovenous treatments have emerged over the past several years. Endovenous treatment as it relates to varicose veins can best be defined as a minimally invasive, catheter-based technique that inflicts endothelial damage to a target vessel to produce thrombosis, fibrosis, and complete eradication of the vessel. The most notable endovenous advancements are:

Radiofrequency ablation (RFA) and endovenous laser ablation (ELA). These methods have demonstrated clinical superiority to stripping and surgical ligation, as well as significantly less postoperative pain and recovery time.

TREATMENT SELECTION

Accepted endovenous treatment modalities include endovenous thermal ablation, sclerotherapy, cutaneous lasers, and IPL devices. Although each treatment modality has its specific advantages and indications, there is significant overlap. When considering a treatment algorithm, the clinician must be selective and base decisions on the needs of each individual patient. The primary goal in treating venous insufficiency is to first treat the highest point of reflux. Additional goals include eradication of all diseased varicosities, minimization of complications, relief of symptoms, and attainment of satisfactory cosmetic results.

| Type of Treatment | Vessels Treated |
|---------------------------|----------------------------|
| Radiofrequency ablation | Saphenous vein trunks |
| | Saphenous vein tributaries |
| | Anterior thigh circumflex |
| | Intersaphenous vein |
| | Perforators |
| Endovenous laser ablation | Saphenous vein trunks |

Endovenous Options for the Treatment of Reflux

| Type of Treatment | Vessels Treated | | | |
|------------------------------------|---|--|--|--|
| | Saphenous vein tributaries | | | |
| | Anterior thigh circumflex | | | |
| | Intersaphenous vein | | | |
| | Perforators | | | |
| | Saphenous vein trunks | | | |
| Ultrasound-guided sclerotherapy | Saphenous vein tributaries | | | |
| | Anterior thigh circumflex | | | |
| | Intersaphenous vein | | | |
| | Perforators | | | |
| | Varicose veins not connected to saphenous vein trunks | | | |
| | Varicose veins | | | |
| Visual or surface sclerotherapy | Reticular veins | | | |
| | Telangiectases | | | |
| Cutaneous lasers and intense | Reticular veins less than 2 mm | | | |
| pulse light | Telangiectases | | | |

RADIOFREQUENCY ABLATION

RFA is an emerging minimally invasive technology that provides efficacious treatment of venous reflux with minimal discomfort and downtime for patients. One of the primary advantages of RFA is that the current procedure can be performed in an outpatient office setting under local tumescent anesthesia. As discussed earlier, the latest RFA technique includes several improvements over the original technology and features a "segmental ablation" method using the ClosureFAST system that is designed for treating both the GSV and SSV.

The Closure FAST catheter is constructed with a 7-cm bipolar electrode affixed to its distal end. The mechanism is such that the electrode must make direct contact with the vein wall to deliver radiofrequency energy. Contact with wall results in destruction of the endothelium, occlusion by contraction of vein wall collagen, and thrombus formation. Eventually, fibrosis occurs within the vein, as well as the formation of new collagen matrix, which further constricts the vein lumen and successfully occludes the vein.

RFA is indicated for superficial vein reflux of the lower extremity; contraindications include superficial venous thrombosis, deep venous thrombosis, aneurysm, and an ankle-brachial index of less than 0.9. Though having a pacemaker is not listed as a contraindication, there is

concern regarding use of RFA in patients with pacemaker. The patient's cardiologist should be consulted before the procedure.

Preoperative Planning

Patient should be well hydrated to achieve maximum distention of the leg veins. In preparation for procedure, DUS is performed to mark the skin overlying the target treatment vein. A surgical marking pen is used to avoid accidental tattooing of the skin. Under DUS, the highest point of reflux is marked and serves as a guide during the RFA procedure. When performing ultrasound it is advisable to heat the ultrasound gel before placing it on the patient's leg because cold gel could cause venospasm. Similarly, the patient should be kept warm and comfortable in the procedure room to further avoid venospasm. Mild sedation such as alprazolam, diazepam, or lorazepam may be prescribed for patients who exhibit anxiety.

Radiofrequency Ablation Procedure

An access site that will allow successful treatment of all possible diseased segments of the target vein is identified ultrasonically. For ablation of the GSV, access is routinely initiated at or just below popliteal area. With the patient in the reverse Trendelenburg position, lidocaine is administered at the selected site and a percutaneous technique with a 21gauge needle is used to gain access under ultrasound guidance. A small cut-down may be used but is not the preferred technique because of cosmetic concerns. A 0.018-inch guide wire is inserted into the GSV and the needle is removed.

Next, a 7 Fr ý 7-cm or 11-cm sheath is advanced over the wire, the 0.018-inch wire is removed, and the 7 Fr ClosureFAST catheter is inserted. The catheter is advanced to the predetermined point at which treatment will begin. If the catheter does not advance easily, a 0.025-inch guide wire may be back-loaded into the device to assist in passage. When treating GSV, optimal positioning of the catheter tip is just below the ostium of the superficial epigastric vein or 2 cm below the SFJ, whichever is more peripheral.

After correct placement of the catheter tip is confirmed by ultrasound, perivenous tumescent anesthesia is administered under ultrasound guidance along the entire target treatment length to create a fluid layer around the GSV. Proper administration of tumescent anesthesia is a critical component of the procedure because it not only serves as an anesthetic but also compresses the vein around the catheter and protects the surrounding tissue from heat damage.

The type of needle used is based on user preference; popular choices include a 25-gauge hypodermic needle or a 22-gauge spinal needle. The needle is connected to a 20-mL syringe, 20-mL refillable syringe, or specialized tubing that is used in conjunction with an infusion pump.

In addition to tumescent anesthesia, a technique that is crucial for success of the procedure is apposite compression. In instructions for use of the ClosureFAST system, VNUS recommends that compression be applied with the ultrasound transducer positioned longitudinally over the heating element, as well as with two fingers distal to the transducer. When prepared to begin, the generator is turned on and the unit is ready to use. With the segmental ablation technique of the ClosureFAST system, each 7-cm segment is treated independently for a 20-second treatment interval.

Radiofrequency energy is delivered by pressing the button located on the handle of the catheter; once a 20-second interval is complete, delivery of energy will automatically stop. The initial treatment segment 2 cm inferior to the SFJ requires two 20-second cycles to ensure successful ablation. Additionally, aneurysmal or large-diameter segments may be treated twice at the user's discretion. For each 20-second cycle, the temperature must reach 120ý C within 5 seconds after the initiation of delivery of the energy; if this temperature is not achieved within the stated time frame, the segment must undergo another 20-second treatment cycle. The RFG Plus generator monitors all parameters during the treatment cycle and alerts the user if the parameters are not successfully met. A segment should not undergo more than three treatment cycles.

On completion of each 7-cm segment, the catheter is repositioned to the contiguous segment by using the 6.5-cm stepped markers on the catheter shaft. The 6.5-cm spacing allows 0.5-cm overlap of each segment to ensure that no untreated areas are left between segments. This process is repeated until the desired vessel length is treated and can last from 1 to 5 minutes, depending on the length of the vessel and the number of repeated segments. When positioning the catheter for the final segment, the user should avoid pulling the heating element into the sheath because it may melt the sheath. After treatment, duplex ultrasound is used to assess the treated vein for absence of reflux and evidence of occlusion.

Discharge and Follow-up

Postoperative compression with a 30 to 40 mm Hg graduated stocking is recommended for at least 1 week. Patients are instructed to ambulate after the procedure before leaving the facility. A DUS followup examination is advised at 72 hours after the procedure to inspect for extension of thrombus into the deep system and to assess the treated veins. Further follow-up evaluations are performed according to physician preference; experts advocate examination at 3 months, 6 months, and 1 year after ablation.

Complications

Potential complications may include vessel perforation, thrombosis, pulmonary embolism, phlebitis, infection, nerve injury, and skin burns or discoloration.

ENDOVENOUS LASER ABLATION

ELA has many similarities to RFA, with the primary differences related to catheter and mechanism used to ablate the vein. ELA uses a 600-ým bare-tipped or jacket-tipped fiber to deliver laser energy to a target area and form steam bubbles within vein lumen. The steam bubbles generate heat within the lumen of the target vessel, which destroys the endothelial lining of the vessel. This causes an inflammatory reaction resulting in a thrombotic occlusion that effectively closes off the vein and eventually leads to fibrosis.

Laser Wavelengths

Numerous different endovenous laser wavelengths have been used to generate endothelial destruction of varicose veins, including 810, 940, 980, 1064, 1319, 1320, and 1470 nm. Since the advent of endovenous lasers, there have been several theories centered around the efficacy of wavelengths absorbed by water and hemoglobin. Research on the optical properties of blood has shown that different wavelengths have variable absorption characteristics:

Endothermal Ablation Devices

| | Diomed Delta Laser* | Vascular Solutions VariLaser | Dornier Medilas-D | AngioDynamics 980 Plus | Sciton Pro-V | CoolTouch CTEV | Biolitec ELVeS PL | VNUS ClosurePlus | VNUS Closure <i>FAST</i> |
|---------------------------------|--|--|--|--|---|--------------------------------|--|--|--|
| Generator type | 810-nm diode laser | 810-nm diode laser | 940-nm Nd : YAG laser | 980-nm diode laser | 1319-nm Nd : YAG laser | 1320 nm | 1470 nm | Radiofrequency original | Radiofrequency segmental |
| Output | 15 or 30 W | 15 W | 120 W | 15 W | 15 W | 10 W | 15 W | 85ý | 120ý |
| Delivery device | Bare-tipped 600- ým fiber | Jacket-tipped 600-ým fiber | Bare-tipped 600- ým fiber with Laser Fiber Protection System (LPS) | Jacket- tipped 600- ým fiber | Bare-tipped 600-ým fiber | Bare-tipped 600-ým fiber | Bare-tipped 600- ým fiber | Multiple thermocouple electrode probes | Single thermocouple electrode |
| Mechanism of energy delivery | Emitting face of fiber makes contact with and destroys endothelium | Formation of steam bubbles generates intraluminal heat and destroys endothelium | Formation of steam bubbles generates intraluminal heat and destroys endothelium | Formation of steam bubbles generates intraluminal heat and destroys endothelium | Endothelial cells absorb light and generate heat that collapses vein walls | Coagulates endothelium | Intracellular water in endothelium and blood absorbs laser energy and occludes vessel | Probes make contact with endothelium and deliver energy that contracts vein wall collagen | Singular electrode makes contact with endothelium and delivers energy that contracts vein wall collagen |
| Catheter/sheath size | 4 Fr | 5 Fr | None | 4 Fr | None | None | None | 6 or 8 Fr | 7 Fr |

| | Diomed Delta Laser* | Vascular Solutions VariLaser | Dornier Medilas-D | AngioDynamics 980 Plus | Sciton Pro-V | CoolTouch CTEV | Biolitec ELVeS PL | VNUS ClosurePlus | VNUS Closure <i>FAST</i> |
|--|---------------------------|------------------------------------|---------------------------|---|---------------------|---|------------------------|---|--|
| Catheter/sheath markings | Every centimeter | Every centimeter | None | Every centimeter; 1-mm markings on distal tip | None | None | None | Every centimeter | Every 6.5 cm |
| Over-the-wire system | Yes (0.035 in) | Yes (0.035 in) | Sheath dependent | Yes (0.035 in) | Sheath dependent | Sheath dependent | Sheath dependent | Yes (0.025 in) | Yes (0.025 in) |
| Access system | Micro-access set | Micro-access set | None | Micro- access set | None | None | None | 18-gauge needle or micro-access set | 18-gauge needle or micro-access set |
| Aiming beam | Adjustable red beam | Adjustable red beam | Adjustable red beam | Adjustable red beam | Adjustable red beam | Adjustable red beam | Adjustable red beam | None | None |
| Manufacturer- recommended pullback | 1 cm every 3-5 seconds | 50-70 J/cm | 1 cm every 3-5 seconds | 50-80 J/cm | Unknown | Automated fiber pullback device at 1 mm/sec | Unknown | 1-2 cm/min (15-20 minutes total) | 20 seconds per 7-cm segment (3-5 minutes total) |
| Compression during procedure | No | No | No | No | No | No | No | Yes | Yes |
| Maximum vein size | None | None | None | None | None | None | None | Unknown | Unknown |

- The 810-nm wavelength is specific for hemoglobin absorption.
- The 940-nm wavelength provides a balanced ratio between the light irradiated into tissue and its absorption by hemoglobin and water.
- The 980-nm wavelength is specific for hemoglobin and water.
- The 1319/1320-nm wavelength is specific for water absorption, and it targets collagen in the vein wall.
- The 1470-nm wavelength features an absorption coefficient in water that is 40 times greater than that of the 810- and 980-nm wavelengths.

Preoperative Planning

Preoperative planning for ELA is virtually identical to that for RFA. An indelible marking pen is used to mark incompetent sources of venous reflux under duplex ultrasound guidance. Steps should be taken to avoid venospasm, such as keeping the room warm and the patient warm and comfortable. A mild sedative similar to alprazolam, diazepam, or lorazepam may be prescribed for the patient before the day of the procedure. The sedative can be brought with the patient in the event that it is needed.

Endovenous Laser Ablation Procedure

As with RFA, when treating the GSV, the target access site is at or slightly below popliteal area. Experienced physicians may attempt to gain access lower on the leg if the vein exhibits reflux distally; however, this adds risk to the procedure because the saphenous nerve lies adjacent to GSV within the saphenous compartment in the lower part of the leg. Ablating the GSV in the lower leg region may increase the risk for paresthesia as a result of the proximity of the saphenous nerve. A microaccess set (21-gauge needle, 0.018-inch wire, and microsheath) is used to initiate access. An 18-gauge needle or a cut-down is also effective but not preferred because of the increased risk for trauma to the vessel or venospasm. Once the microsheath is inserted into the GSV, the distance from the access site to SFJ is measured. The inner dilator of the microsheath is removed and a 0.035-inch guide wire is advanced through the microsheath to SFJ under ultrasound guidance. The microsheath is removed and a long sheath is selected on the basis of measured distance from the SFJ to the access site. The sheath selected, most commonly 45 cm in length, is back-loaded over the guide wire to a point just distal to the superficial epigastric vein. Once in place, the inner dilator and guide wire are removed and a 600-ým bare-tipped or jacket-tipped fiber is advanced into the sheath. The fiber is then connected to the generator and the aiming beam turned on to help visualize the fiber tip under the skin. While the fiber is held in place, the sheath is withdrawn to the locking mechanism of the fiber and locked in place, with the tip of the fiber exposed approximately 2 cm past the end of the sheath. Positioning is reconfirmed with ultrasound, and preparation is made to administer tumescent anesthesia. Similar to RFA, tumescent anesthesia is injected

perivenously. with a 22- or 25-gauge hypodermic needle. A handdelivery method, a syringe refill system, or a pump may be used for administration. Hand delivery is the best technique for learning how to perform tumescent anesthesia under ultrasound guidance. I prefer to use a refillable syringe or tumescent pump because it decreases the time needed for delivery of tumescent anesthesia and reduces the number of needle punctures. The volume of fluid delivered is dictated by the distance created between the skin and the vein; the target diameter of fluid around the vein is 10 mm, which can be ensured with ultrasound. Positioning of the laser fiber tip is then reconfirmed before commencing with the procedure.

Procedure Variations

As the endovenous laser procedure has progressed and improved over the past few years, several variations in method have developed. A majority of the variations are related to pullback time and the amount of energy delivered. After the continuous mode replaced the pulsed mode as the preferred mechanism, the initial pullback rates for the laser fiber were 3 mm/sec (18 cm/min). Another popular protocol was a pullback rate of 1 cm every 3 to 5 seconds, which equates to a relatively variable 12 to 20 cm/min. Accurately gauging the pullback rate was challenging because the first sheaths did not contain any type of dashes or marks. Pullback speed was estimated by an assistant calling out increments of time so that the physician could use best judgment. Many experts now focus on total energy delivered and gauge pullback during ELA procedures according to joules delivered per centimeter. This has been termed *linear endovenous energy density*. Currently, 50 to 80 J/cm is the average treatment energy most often used for ELA procedures. Continuous pullback is used while watching the real-time energy readout on the generator and gauging speed with 1-cm marks on the sheath. This method has proved to be more consistent than using time to gauge pullback because the same amount of energy is delivered in each case.

Once tip positioning is confirmed, the laser is switched from standby to ready mode and the foot pedal is depressed to deliver energy. While using the preferred method to gauge pullback, the laser fiber and sheath are drawn through the vessel simultaneously in a continuous fashion. Treatment is stopped by removing one's foot from pedal when the tip of the laser fiber is approximately 1 to 3 cm above the entry site to prevent skin burns or trauma to the entry site. Closure of the vein is visualized with duplex ultrasound, followed by removal of the fiber and sheath.

Discharge and Follow-up

The entry site is covered with Steri-Strip cut into thirds and dressed with a sterile gauze pad. Patients are fitted with a 30 to 40 mm Hg graduated stocking and instructed to wear the stocking continuously for the first 24 hours. After this initial period the stockings are worn during nonsleeping hours for a period of at least 1 week. Patients ambulate immediately to promote the vessel occlusion process and decrease the incidence of DVT. NSAIDs may be taken daily as needed for the first 7 to 10 days after the procedure. DUS follow-up examination is performed according to surgeon's preference; however, evaluation within 72 hours to 1 week after the procedure is recommended for assessing the treated veins and inspecting for DVT.

Complications

Potential complications may include but are not limited to vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, skin pigmentation, neovascularization, paresthesia, complications from tumescent anesthesia, irradiation of nontarget tissue, hemorrhage, necrosis, skin burns, and pain.

SCLEROTHERAPY

Sclerotherapy can be used to treat a myriad of vein types and sizes, although it is most commonly used to treat smaller vessels such as the reticular veins and telangiectases. Sclerotherapy is best defined as the introduction of a chemical into the lumen of a vein to induce endothelial damage that results in thrombosis and eventually fibrosis. Considered the most versatile treatment option for venous ablation, sclerotherapy can be used to treat a large range of vein sizes from telangiectases to large varicose veins. With the advent of the radiofrequency and endovenous laser procedures, the primary intent of sclerotherapy is to effectively eliminate the target vein after the highest point of reflux is treated with one of these new modalities.

Sclerotherapy entails several different methods to deliver a sclerosing agent, depending on the diameter of the target vein. For smaller veins such as telangiectases, venulectases, and small reticular veins, liquid sclerotherapy is used to deliver injections directly into the target vein. Larger reticular veins and other varicose veins may also be treated by liquid sclerotherapy with a higher concentration of sclerosing agent or by foam sclerotherapy. Foam sclerotherapy involves the addition of air to a detergent sclerosing agent by means of agitation to produce a foam-like consistency, which allows enhanced contact with vein wall on injection. Because the sclerosing agent must make contact with vein wall to cause endothelial damage, the primary limitation of sclerotherapy is vein diameter. Effective interaction with vein wall may be encumbered by blood flow within larger veins dissipating the agent. An innovative method using a catheter to deliver sclerosants has also emerged as an option for larger veins. There several indications are and contraindications to be cognizant of before performing sclerotherapy.

Sclerosing Agents

Sclerosing agents are most commonly grouped into categories based on their mechanism of action for producing endothelial damage. Categories of currently available solutions include osmotics, alcohol, and detergents. Ideal sclerosing agents can effectively damage the endothelium, exhibit a low incidence of adverse events, and are painless to inject. Relative contraindications to sclerotherapy include but may not be limited to asthma, late complications of diabetes, hypercoagulable state, leg edema, advanced peripheral arterial occlusive disease, and chronic renal insufficiency. Absolute contraindications are a known allergy to the sclerosant, acute cellulitis, acute respiratory or skin disease, disease. phlebitis migrans. severe systemic acute superficial thrombophlebitis, pregnancy, hyperthyroidism, and bedridden status.

Comparison of Sclerosing Agents

| Agent | Manufacturer | Category | FDA Approval | Strength | Advantages | Disadvantages | |
|---|--|-----------|------------------|----------|---|---|--|
| Hypertonic saline | Multiple | Osmotic | Off-label use | ++ | Low risk of allergic reaction, wide availability, rapid response | Off-label, painful to inject, hyperpigmentation, necrosis, rapid dilution, not recommended for facial veins | |
| Sclerodex (hypertonic saline and dextrose) | Omega Laboratories , Canada | Osmotic | Not approved | ++ | Low risk of allergic reaction, low risk of necrosis, high viscosity | · · | |
| Chromex (72% chromated glycerin) | Omega Laboratories , Canada | Alcohol | Not approved | + | Low incidence of hyperpigmentati on, necrosis, and allergic reaction | Not FDA approved, weak sclerosing agent, highly viscous and painful to inject, may cause hematuria at high doses | |
| Nonchromated glycerin | Compounde d at pharmacy | Alcohol | Off-label use | + | Low incidence of hyperpigmentati on, necrosis, and allergic reaction | Weak sclerosing agent, typically only used for telangiectases | |
| Scleromate (sodium morrhuate) | Glenwood, LLC, USA | Detergent | Approved | +++ | FDA approved | High incidence of skin necrosis and anaphylaxis | |
| Sotradecol (sodium tetradecyl sulfate) | Bioniche Pharma, USA (distributed by AngioDyna mics, Inc.) | Detergent | Approved | +++ | FDA approved, low risk of allergic reaction, potent sclerosant | Potential necrosis with extravasation, matting of telangiectases | |
| Aethoxysklerol (polidocanol) | Kreussler Pharma, Germany | Detergent | Not approved | +++ | Very low risk of allergic reaction, painless to inject | Not FDA approved, associated with matting of telangiectases | |

Preoperative Planning

Digital photographs of the target veins should be obtained to document their appearance before sclerotherapy is performed. Larger

target veins such as varicose veins should be traced with a surgical marker with the patient standing because they may be difficult or impossible to identify during supine. Preoperative marking is typically not required for smaller veins such as telangiectases and reticular veins. When sclerotherapy is combined with endothermal ablation of the saphenous veins, sclerotherapy below the knee should be performed second. If a staged approach is used, the GSV or SSV should be treated first, with sclerotherapy following several weeks later. This method allows the existing truncal varicosities to shrink or disappear before further procedures. Several sclerotherapy treatments may be necessary to eliminate the veins, depending on the number and severity of diseased veins. It is important to establish the expectation that several sessions could be required and explain the sclerotherapy process to patients.

Sclerotherapy Procedure

After preoperative preparation, the sclerosing agent is diluted with 0.9% saline according to the size of the vein. Recommendations are the following dilutions in concentration for STS: 0.125% to 0.25% for telangiectases, 0.25% to 0.5% for reticular veins, and 0.5% to 3.0% for varicose vein.

| Sodium Tetradecyl Sulfate (STS) |
|---------------------------------|
|---------------------------------|

| Indications | Recommended STS Concentration |
|---|----------------------------------|
| Varicose veins <8 mm | 0.5%-3.0% |
| Reticular veins 2-4 mm | 0.25%-0.5% |
| Telangiectasias 0.1-2.0 mm | 0.125%-0.25% |
| Recurrent varicosities | 0.5%-3.0% |
| Failed segments of endothermal ablation | 0.5%-3.0% |
| Unsightly veins of the hands and feet | 0.25%-0.5% |
| Congenital malformations | 0.125%-0.25% |
| Vascular malformations | 0.125%-0.25% |
| Facial telangiectases | 0.125%-0.25% |

Liquid Sclerotherapy

After dilution of agent, multiple syringes are filled and assembled with 30-gauge needles for performing liquid sclerotherapy. For best results, veins should be treated from the largest diameter to the smallest and in a proximal-to-distal direction. When injecting at most proximal source, the sclerosing agent flows away from the point of injection.

Ultrasound-Guided Foam Sclerotherapy

Tessari method has been found by many to be a superior technique in which significant coalescence does not begin until after the first 1 to 2 minutes. When diluting an agent for use with the foam method, the final concentration is dependent on the air-to-liquid ratio. For Tessari method, a ratio of one part liquid to four or five parts air has shown excellent stability and efficacy. When using the dilution guidelines given in this section, the smaller value of each range should be used when applying the foam method.

Depending on the size and depth of the target veins, DUS can be helpful in guiding the injection of foamed sclerosants. If choosing to use ultrasound-guided sclerotherapy, incompetent target vein segments should be marked before the procedure. After mapping the treatment area, access to the first vein to be treated is achieved under ultrasound guidance. Access is confirmed by return of blood, and the needle is taped to the patient's leg. The sclerosing agent is prepared by placing one part STS (or the detergent agent of choice) in one syringe to four parts air in the other syringe. The syringes are attached to stopcock, the stopcock is closed off, and the foam solution is created by a rapidly mixing the air and chemical back and forth between the two syringes. This rapid movement of solution from one syringe to other is performed 20 times. After moving most of the solution to one syringe, the filled syringe is connected to the needle, and intravascular positioning is reconfirmed with ultrasound. A small amount of foam should be injected initially to confirm needle placement within the vein under ultrasound. The amount of foam delivered is determined during injection by using ultrasound to visualize when the targeted vein is filled with foam. On completion the needle is removed, and folded 2 \pm 2-inch gauze is secured over the injection site with adhesive tape.

Discharge and Follow-up

Recent studies have demonstrated increased efficacy with post procedure compression. Weiss and coworkers evaluated various lengths of compression and found a strong correlation between compression time and efficacy, as well as side effects; patients undergoing 3 weeks of continuous compression demonstrated the most improvement. Subsequent to ambulation, patients can be discharged from the facility. They may return to activities of daily living but should avoid heavy aerobic exercise that would involve the lower extremities for a period of 2 weeks.

Complications

Complications typically includes hyperpigmentation, telangiectatic matting, pain with injection, and urtication after injection.

Rarely observed are more serious complications, including but perhaps not limited to cutaneous necrosis, superficial thrombophlebitis, nerve

damage (saphenous, sural), allergic reaction (anaphylaxis), DVT, pulmonary embolism, and inadvertent arterial injection.

TREATMENT OF PERFORATOR VEIN INCOMPETENCE

The recent development of treatment options for reflux in superficial veins has established new standards for when patients can be treated as outpatient without the need for general anesthesia. These treatment options allow patients to ambulate immediately after treatment with less postoperative pain and almost no negative impact on quality of life. In this new environment, the invasiveness and risk for wound complications associated with previously considered minimally invasive SEPS exceed that of the treatment of saphenous veins. New modalities such as ultrasound-guided percutaneous ablation of perforating veins with sclerosing solutions or thermal energy are becoming increasingly popular.

During such a short history, the outcomes of IPV treatment and the role of IPVs in venous pathology were questioned and disputed. Although evidence provides a substantial basis for decision making in management of patients with varicose veins, it would be fair to state that the impact of IPVs on the natural history of varicose veins and the indications for elimination of PV reflux remain to be defined more precisely.

INDICATIONS FOR INTERRUPTION

Precise definition of the indications for interruption of perforator incompetence is necessary in clinical practice because it provides a basis for assessment of treatment outcomes. Although definitive studies to identify when IPV interruption should be considered are yet to be conducted, one or more of the following reasons can serve as the indication for treatment of IPVs.

- 1. Promotion of ulcer healing in extremities with CEAP clinical class C6
- 2. Prevention of ulcer recurrence in extremities with clinical classes C5 and C6
- 3. Diminution of the severity of CVD and resolution of symptoms in C2S to C5S extremities
- 4. Prevention of progression to more advanced stages in C2 to C4 extremities.

The presence of an IPV alone does not justify interruption. The decision to intervene should be based on clinical judgment and assessment of the role of a specific IPV in the overall hemodynamic picture of the extremity. The benefits of interruption and the risks of leaving this PV untreated should also be considered.

OPERATIVE PLANNING AND OPTIONS

The timing and technique of IPV interruption are important. Although procedures can be staged, performing simultaneous saphenous vein ablation and perforator ablation has two major advantages. First, all invasive procedures are performed in one session, which is highly appreciable by the patient. Second, it has been suggested that any remaining incompetent tributaries and IPVs connected to the saphenous veins can increase the chance of recanalization after thermal and chemical ablation. Thus, treating IPVs at the time of saphenous vein ablation possibly improves the result of the saphenous vein ablation. When simultaneous treatment of IPVs and incompetent saphenous veins is planned, selection of the IPV interruption technique is very much dependent on the method of treating the saphenous vein. The less invasive options for saphenous ablation limit the use of open surgical interruption because it may increase immediate postoperative morbidity and negate the advantages of minimally invasive procedures. When IPV interruption is performed alone, selecting a minimally invasive option still has the advantage of minimizing immediate postoperative morbidity and thereby allowing early ambulation and having less of an impact on quality of life.

OPEN SURGERY

Interruption of PVs through small stab wounds plus avulsion by a vein hook is now preferred among the open surgical methods because this procedure is significantly less invasive and does not require hospitalization. With this technique, duplex scanning is used for preoperative mapping and the IPVs are marked on the skin, which allows performance of a more precise procedure. Ligation of incompetent perforators can also be done by making a short incision directly over the marked sites and ligating them at the fascia with absorbable sutures. Alternatively, vein hook position can be controlled with the use of intraoperative transcutaneous ultrasound to ensure that a targeted IPV is actually interrupted. Selection of an open perforator interruption technique does not guarantee 100% success. Five percent of perforators are usually missed, and 32% recur within 3 years, half of them being incompetent.

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Subfascial Endoscopic Perforator Surgery



SEPS uses endoscopic instrumentation to achieve interruption of incompetent perforators through small incisions placed remotely from areas of lipodermatosclerosis or ulceration. First described by Hauer in the 1980s. SEPS became the most accepted surgical treatment of advanced stages of chronic venous insufficiency because of its minimally invasive nature and safety profile when compared with the classic, more extensive Linton procedure. SEPS can be performed through one or two endoscopic ports; the two-port technique uses a 10-mm port for the camera and a 5-mm port for the instrumentation. Adding the second 5-mm port is favored by most authors because it does not significantly increase the morbidity of the procedure, and it facilitates work in the narrow subfascial space. The limb is elevated and rested on a leg holder, the field is made bloodless by exsanguination of the limb with an Esmarch bandage, and a thigh tourniquet is inflated to 300 mm Hg. The 10-mm port is placed in healthy skin on the medial aspect of the calf,

10 cm distal to the tibial tuberosity. A small longitudinal skin incision is performed first and the subcutaneous tissues are sharply dissected until the fascia is encountered; the fascia is then grasped with mosquito clamps and incised longitudinally as well. Care must be taken to avoid creating too large an opening because this may lead to gas leak during the procedure and consequently poor visualization. Balloon dissection may be used to facilitate passage through the subfascial space and help with initial access through the ports. The camera is inserted through the first port, and then a second 5-mm port is inserted under vision about 10 to 12 cm distal and posterior to the first port, halfway between the main port and the ankle. Carbon dioxide is insufflated to enlarge and optimally visualize the subfascial space, with pressure maintained around 30 mm Hg. Initial tissue dissection is performed with endoscopic scissors inserted through 5-mm port, and the areolar tissue between the calf muscles and the superficial fascia is sharply divided. All visualized perforators encountered from the medial border of the tibia to the posterior midline are interrupted with one's preferred technique, such as the harmonic scalpel, electrocautery, or division with scissors between metallic clips. A sharp paratibial fasciotomy should routinely be performed before identification and division of the perforators because the posterior tibial perforators are often located in the deep posterior compartment, behind paratibial fascia or within the intermuscular septum. More proximal paratibial perforators may be visualized better by exposing the medial insertion of soleus muscle on the tibia. It is important

during this step to remain close to tibia to avoid injury to the posterior tibial vessels and the tibial nerve. A technical limitation is the presence of retromalleolar perforators, which cannot be reached this way and need to be treated by an open technique with a separate incision. On completion of the procedure, the ports and instrumentation are removed, the tourniquet is deflated, and the CO_2 is manually expressed from the subfascial space. If varicose stab avulsions are performed at the same time as SEPS, the tourniquet is kept inflated to control bleeding. A compressive bandage is applied, and patients can be discharged after a few hours of observation.

MATERIALS AND METHODS

Around 60 patients with varicose veins will be selected from the patients attending out-patient clinic in Rajiv Gandhi Govt. General Hospital, Madras Medical College. All patients will be explained about the disease, benefits & possible side effects of treatment. Informed written consent will be obtained from all patients before initiation of treatment. Detailed history will be obtained and patients will be evaluated as follows

- 1) General and systemic examination.
- Investigations namely complete hemogram, liver function tests, renal function tests and chest xray.
- Abdominal Ultrasound, Doppler study of both lowerlimbs (arterial & venous)

The study will be prospective hospital based time boundstudy. All those cases which satisfy the inclusion criteria will be included in this study. Duration of study will be from June 2015 to Sept. 2015.

Inpatients of Rajiv Gandhi Govt. General Hospital who are undergoing elective varicose vein surgery fulfilling the inclusion criteria will be taken into study after obtaining informed written consent. The cases will be randomly divided in three groups, based on the mode of management for SFJ incompetence.

Group-A patients will be treated with high ligation of great saphenous vein.

Group-B patients will be treated with ligation of great saphenous vein along with stripping from groin to knee and

Group-C patients will be treated with Radiofrequency ablation of great saphenous vein.

In all three groups perforators incompetence will be managed with stab avulsion

SUBJECT SELECTION:

INCLUSION CRITERIA:

- 1. Patients who have given informed and written consent.
- 2. Age of the patient: 18 -50 years.
- 3. Primary varicose veins.

EXCLUSION CRITERIA:

- 1. Age <18 years or age > 50 years.
- 2. Secondary varicose veins.
- 3. Patients with venous ulcer.

SCREENING PROCEDURES / VISITS:

Patients will be reviewed immediate postoperatively, after 6 weeks and 3 months after surgical procedure

Following factors will be compared....

- Duration of Procedure
- Post operative pain score
- Limb oedema
- Wound infection
- Duration of hospital stay
- Localized haematoma & Skin changes

RESULTS:

Statistical analysis plan: Data obtained will be analysed using appropriate statistical package with due consultation with the Statistician.

OBSERVATION AND ANALYSIS

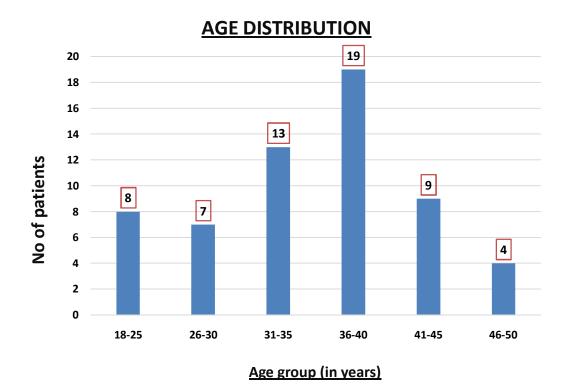
AGE DISTRIBUTION

| AGE GROUP (years) | NO. OF PATIENTS |
|-------------------|-----------------|
| 18-25 | 8 |
| 26-30 | 7 |
| 31-35 | 13 |
| 36-40 | 19 |
| 41-45 | 9 |
| 46-50 | 4 |

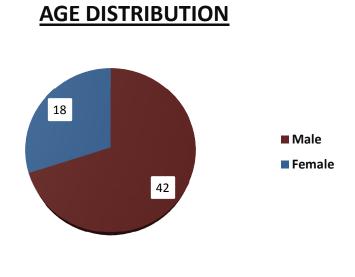
Sex Distribution

Male - 42

Female - 18

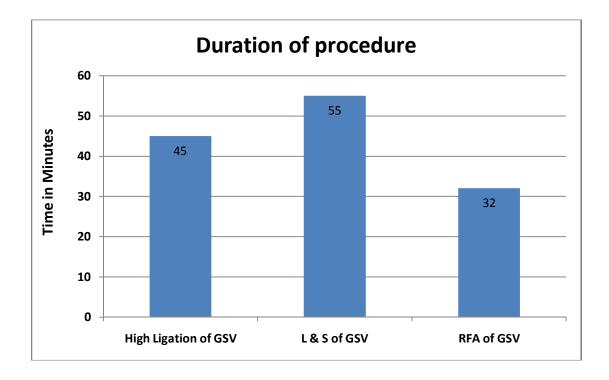


As per the age is concerned, most of the patients in this study are between 30-40 years old and considering sex, two-third of the patients are males.



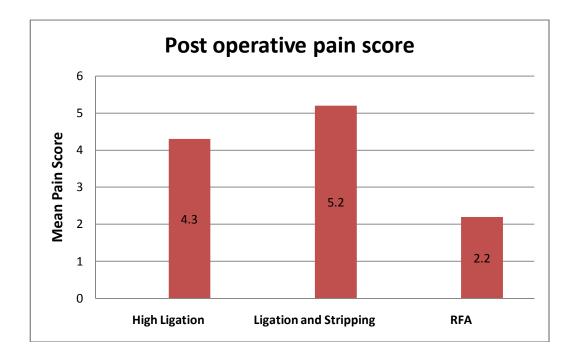
Duration of Procedure:

In patients treated with flush ligation of GSV alone, mean time duration was around 45 minutes. In case of patients treated with Ligation and stripping of GSV, mean time duration was 55 minutes, but in patients treated with RFA of GSV, mean time duration was 32 minutes only.



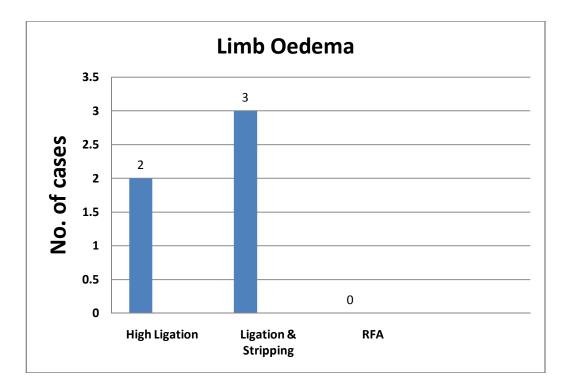
Post operative pain score:

Post op pain score was calculated by Visual Analog Scale with '0' as no pain and 10 as maximum pain. In patients treated with ligation of GSV alone mean pain score was 4.3. In case of ligation and stripping of GSV, mean pain score was 5.2 and in RFA of GSV, it was 2.2.



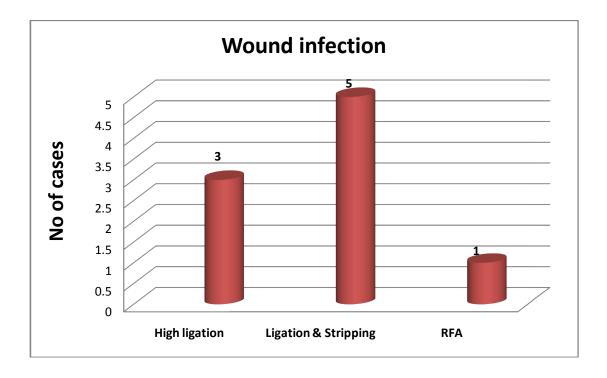
Limb Oedema:

Oedema of operated limb developed in 2 cases treated with ligation of GSV alone, 3 cases of ligation and stripping of GSV and none of the patients treated with RFA developed limb oedema.



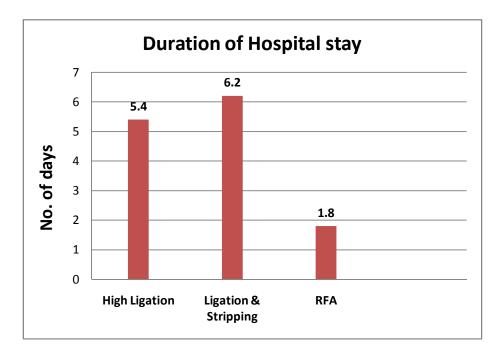
Wound infection:

In case of patients treated with ligation of GSV alone 3 patients developed wound infection, 5 patients developed wound infection in patients treated with ligation and stripping of GSV and only 1 patient developed wound infection at the catheter inserted site in RFA category.



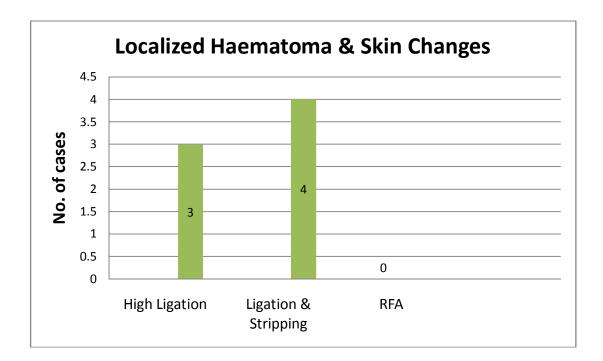
Duration of Hospital stay:

In case of patients treated with ligation of GSV alone, mean hospital duration of stay was 5.4 days. In patients with ligation and stripping of GSV, mean hospital duration of stay was 6.2 days including the pre op evaluation and assessment work up in both cases. But in patients treated with RFA, mean hospital duration was only 1.8 days.



Localized Haematoma & Skin Changes:

Localized haematoma developed in 3 patients treated with Ligation of GSV alone, 4 patients of ligation and stripping of GSV, but none of RFA patients developed localized haematoma and any type of skin changes.



DISCUSSION

In duration of procedure, we haven't included the anaesthetic preloading or induction time in any of three categories. As we use CLOSURE FAST RFA device, it does segmental ablation, so patients treated with RFA comparatively less procedure time than patients treated with ligation of GSV alone and ligation and stripping of GSV.

Considering **Post operative pain score**, Patients treated with conventional surgery needed IM voveran on post op day 1 and 2 sometimes, but patients treated with RFA needed only oral analgesics.

In case of **limb oedema** of operated limb, RFA patients in this study did not have any limb oedema, but some of the patients treated with conventional surgery developed limb oedema which needed tight compression stockings, limb elevation and sometimes even anti oedema measures.

Wound infection: In conventional surgery cases, some patients developed wound infection, which was considered to be due to poor preparation of operative site, localized fungal infections and poor post op wound care. But in RFA patients, only one patient developed wound infection at catheter insertion site.

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Duration of hospital stay: It was comparatively longer in patients treated with conventional surgery as those patients needed detailed lab investigations, pre op evaluation and assessment work up. But RFA patients needed only pre op Duplex scan and anaesthetic fitness.

Localized Haematoma & skin changes: This was developed only in patients treated with conventional surgery and probably the same cause was attributed as in wound infection cases.

CONCLUSION

RFA is a minimally invasive procedure. Its potential early benefits, by avoiding groin dissection and GSV stripping, have been confirmed by the findings from this study.

Patients experienced less pain and recovered more quickly, which was reflected in better patient satisfaction and Quality of life outcomes following RFA.

RFA involves considerably less tissue dissection and trauma. Patients who had RFA experienced considerably less pain, required less analgesia and were able to return to their activities more quickly. This improved confidence, lifestyle, social contacts, cosmesis, QoL and satisfaction in the early days after RFA procedure can be considered significantly better than in patients undergoing conventional surgery.

The most common reason for dissatisfaction was postoperative morbidity, after conventional surgery illustrating the impact of adverse sequelae. QoL was significantly better after both interventions. Scores were, however, consistently higher after RFA.

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PROFORMA

PATIENT DETAILS:

| Name: | Age: | Sex: |
|---|-----------|------|
| IP No. : | | |
| <u>ON ADMISSION:</u> Main Complaints : | | |
| Duration of Complaints : | | |
| Co – Morbid Illness : | | |
| Significant Past History : | | |
| CLINICAL EXAMINATION: | | |
| Pulse : | BP: | |
| RR: | Temp : | |
| Pallor : | Icterus : | |
| CVS : | RS : | |
| P/A : | | |
| L/E: | | |

INVESTIGATIONS :

CBC:

ESR:

Liver Function Test :

Renal Function Test :

CXR :

USG Abdomen:

Doppler Lower limb:

TREATMENT :

Post operative complications:

| | | | HIGH | LIGATION | OF | GSV | | | |
|----------|--------------|---------|--------|---------------------------------|---------------|----------------|--------------------|-------------------------|-----------------|
| S.N 0 | Name | Age/Sex | I.P.no | Procedure duration (mins) | Pain score | Limb oedema | Wound infection | Hospital stay (days) | Skin changes |
| 1 | Ramesh | 38/M | 56373 | 48 | 4 | 1 | I | 5 | ı |
| 2 | Moorthy | 27/M | 66643 | 42 | 5 | I | I | 9 | I |
| 3 | Munusamy | 49/M | 77282 | 47 | 5 | I | I | 5 | ı |
| 4 | Renuka | 32/F | 74622 | 43 | 5 | | - | 7 | I |
| 5 | Durai | 39/M | 63677 | 50 | 6 | + | I | 5 | + |
| 9 | Devaraj | 41/M | 45657 | 51 | 4 | I | + | 8 | ı |
| 7 | Thangavel | 22/M | 58674 | 42 | 4 | ı | I | 5 | |
| 8 | Ayesha | 42/F | 67998 | 40 | 3 | I | I | 9 | ı |
| 6 | Suriya | 35/M | 70004 | 41 | 3 | ı | ı | 4 | |
| 10 | Anwar basha | 35/M | 65740 | 49 | 4 | I | I | 4 | + |
| 11 | Aravindh | 23/M | 60126 | 50 | 7 | + | + | 6 | |
| 12 | Ravichandran | 48/M | 66632 | 42 | 5 | I | I | 5 | |
| 13 | Chandra | 33/F | 58409 | 44 | 5 | ı | ı | 4 | |
| 14 | Angammal | 38/F | 57843 | 46 | 4 | | | 5 | |
| 15 | Joseph | 44/M | 50768 | 41 | 7 | | + | 6 | + |
| 16 | John | 26/M | 49757 | 39 | 4 | | ı | 5 | |
| 17 | Muniyammal | 39/F | 63878 | 40 | 3 | | ı | 5 | |
| 18 | Janardhanan | 42/M | 75386 | 45 | 2 | | ı | 4 | |
| 19 | Shalini | 33/F | 80175 | 52 | 3 | | ı | 5 | |
| 20 | Murali | 26/M | 73298 | 48 | 3 | ı | ı | 5 | |

| | Skin changes | I | I | I | I | + | I | I | I | I | + | I | I | I | I | + | I | I | I | I | + |
|-------------------|---------------------------------|-----------|-------|-------|-------|----------|--------------|-------|-------|-------|---------|---------|-------|---------|---------|------------|----------|-----------|-------|------------|------------|
| | Hospital stay (days) | 5 | 9 | 4 | 6 | 11 | 5 | 5 | 4 | 5 | 7 | 8 | 7 | 9 | 10 | 5 | 4 | 4 | 6 | 6 | 7 |
| V | Wound infection | I | I | I | + | + | I | I | I | I | I | + | I | I | + | I | I | I | + | I | I |
| NG OF GSV | Limb oedema | • | - | - | • | + | - | - | - | - | + | - | - | F | - | - | - | I | + | I | I |
| STRIPPING | Pain score | 4 | 4 | 2 | 9 | 7 | 4 | 3 | 4 | 3 | 8 | 7 | 3 | 5 | 9 | 5 | 9 | 5 | 8 | 5 | 6 |
| HIGH LIGATION AND | Procedure duration (mins) | 60 | 53 | 58 | 51 | 62 | 50 | 52 | 55 | 53 | 55 | 56 | 57 | 49 | 51 | 54 | 56 | 61 | 59 | 51 | 57 |
| IGH LIGA | I.P.no | 64281 | 54321 | 47892 | 63415 | 71109 | 56478 | 70985 | 66543 | 62515 | 59986 | 49876 | 52320 | 48875 | 61233 | 70452 | 80123 | 77652 | 56321 | 61874 | 59873 |
| Η | Age/Sex | 37/M | 42/M | 33/F | 43/M | 37/M | 36/F | 27/M | 33/F | 40/M | 39/M | 47/M | 44/F | 30/M | 36/F | 42/F | 39/M | 37/M | 25/F | 32/M | 24/M |
| | Name | Sivakumar | Ramu | Nisha | Azhar | Anbumani | Shakira banu | Gokul | Rekha | Kumar | Murugan | Moorthy | Gowri | Shankar | Bhavani | Chandramma | Hidayath | Devendran | Rani | Venkatesan | Srinivasan |
| | v z o | 1 | 2 | 3 | 4 | \$ | 9 | 7 | 8 | 6 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |

| | | | RADIOI | RADIOFREQUENCY ABLATION OF GSV | CY ABLAT | ION OF G | SV | | |
|------|-------------|---------|--------|---------------------------------------|------------|-----------------|--------------------|------------------------|--------------|
| S.NO | Name | Age/Sex | I.P.no | Procedure duration (mins) | Pain score | Limb oedema | Wound infection | Hospital stay(days) | Skin changes |
| 1 | Sivanesan | 41/M | 50456 | 37 | 2 | - | - | 2 | - |
| 2 | Inbaraj | 34/M | 76284 | 41 | 3 | , | ı | 3 | ı |
| 3 | Lakshmi | 39/F | 63421 | 28 | 2 | , | | 2 | ı |
| 4 | Shanthi | 25/F | 52098 | 32 | 1 | | ı | 2 | ı |
| S | Nagaraj | 27/M | 70123 | 36 | 2 | ı | ı | 1 | ı |
| 9 | Elumalai | 33/M | 63534 | 30 | 3 | | 1 | 2 | ı |
| 7 | Sivagami | 47/F | 57893 | 28 | 4 | ı | ı | 2 | ı |
| 8 | Arunachala | 35/M | 65822 | 37 | 1 | ı | ı | 3 | ı |
| 6 | Ramasamy | 40/M | 71239 | 31 | 2 | ı | + | 2 | ı |
| 10 | Chandru | 22/M | 76583 | 35 | 1 | | | 1 | ı |
| 11 | Subramani | 34/M | 80363 | 28 | 3 | , | | 2 | ı |
| 12 | Gajendran | 36/M | 84123 | 34 | 2 | | ı | 1 | ı |
| 13 | Indhu | 29/F | 65120 | 33 | 4 | ı | ı | 3 | I |
| 14 | Selvaraj | 37/M | 69821 | 27 | 1 | ı | ı | 2 | ı |
| 15 | Selvakumar | 40/M | 58762 | 27 | 3 | | ı | 1 | ı |
| 16 | Rafat jahan | 36/F | 75626 | 29 | 2 | | 1 | 1 | ı |
| 17 | Arun | 24/M | 61628 | 32 | 2 | ı | ı | 2 | ı |
| 18 | Suresh | 39/M | 56563 | 30 | 1 | , | | 1 | ı |
| 19 | Anandhan | 31/M | 58728 | 31 | 2 | , | | 2 | ı |
| 20 | Baskaran | 25/M | 60848 | 34 | 3 | I | ı | 1 | |