Great saphenous vein mechanochemical Sclerotherapy versus Laser ablation in treatment of varicose vein

A Prospective randomized study

Submitted for partial fulfillment of Master Degree
In General surgery
By

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List of abbreviations used

(AAGSV): Anterior Accessory Great Saphenous Vein
(AASV) Anterior Accessory Saphenous Vein
(CEAP): Clinical, Etiological, Anatomic, and Pathophysiological
(CK) : Cytokines
(CVD) : Chronic venous disease
(CVI) : Chronic venous insufficiency
(DUS) : Duplex ultra sonography
(DVT) : Deep venous thrombosis
(ECM) : Extracellular matrix
(EVLA) :Endovenous laser ablation
(GSV) : The great saphenous vein
(MMPs) :Matrix metalloproteinases
(NICE) : National Institute for Health and Care Excellence
(PIN) : Perforate-invaginate technique
(RFS) : Radiofrequency system
(SFJ) : Sapheno-Femoral junction
(SMCs) : Smooth muscle cells
(SPJ) : Sapheno popliteal junction
(SSV) : The small saphenous vein
(VVLE): Varicose veins of the lower extremity
(VCSS) : Venous Clinical Severity Score
(VCSS) : Venous Clinical Severity Score
(VDS) : Venous Disability Score
(VS) : Venous severity
(VSDS) : Venous Segmental Disease Score
(VSS) : Venous Severity Scoring
(VV) : Varicose veins

INTRODUCTION

Varicose veins of the lower limbs are dilated , tortuous, and palpable veins that are typically larger than 3 mm. **(Vandy and Wakefield, 2012).** The veins of the lower limbs are organized into three systems: superficial, deep, and perforating veins. These veins are located in two compartments : The superficial compartment and the deep compartment **(Subramoniam, 2015).**

Altered connective tissue proteins and increased proteolytic enzyme activity appear to be central to the pathophysiology of varicose veins. Abnormalities in vein wall architecture probably precede the development of valvular incompetence and overt varicosities **(Manuel Mayr et al., 2012).**

The clinical presentation of varicose veins varies among patients. Some patients are asymptomatic. Local symptoms include pain, burning, or itching. Generalized symptoms consist of leg aching, fatigue, or swelling. Symptoms are often worse at the end of the day, especially after periods of prolonged standing, and usually disappear when patients sit and elevate their legs. Duplex Doppler ultrasonography is a simple, non-invasive, painless, readily available modality that can assess the anatomy and physiology of the lower extremity venous system **(Richard and Peter, 2008).**

The management of varicose veins includes the use of conservative care, such as with lifestyle changes and compression therapy, and the use of more invasive treatments, such as surgery, endovenous thermal ablation, and sclerotherapy **(Sylvia et al.,2014).**

In the past decade, alternative treatments such as endovenous ablation of the GSV with laser (EVLA), radiofrequency ablation (RFA) and ultrasound-guided foam sclerotherapy (UGFS) have gained popularity. Performed as office-based procedures using tumescent local anesthesia, the new minimally invasive techniques have been shown in numerous studies to eliminate the GSV from the circulation safely and effectively **(Darwood RJ and Gough MJ, 2009).** Fortunately, in most cases, the complaints correlate to reflux in the venous system which can be addressed by conservative, surgical, or interventional treatment options. Conservative treatment includes the use of medical graduated stockings or more sophisticated compression bandages. The surgical treatment of saphenous varicose veins

is one of the very few treatments that barely changed since its invention more than a hundred years ago. In 1884, the German surgeon Madelung invented a radical operation to extirpate the great saphenous vein (GSV) and its perforators through one long skin incision from groin to ankle. In 1905, the American surgeon William Keller introduced the stripping technique using a wire and multiple small incisions. Since then, physicians refrained from the long skin incision ***(Keller, 1905)***. William Babcock invented the method of vein surgery using a vein stripper ***(Babcock w,1907)*.**

The Babcock procedure, which has remained standard varicose vein surgery for over 100 years, includes great saphenous vein ligation, stripping and phlebectomy ***(Winterborn et al., 2008)***. Yet, it is associated with relatively high rates of such complications as pain, hematoma, wound infection, lymphocele, lymphorrhoea or neuropathies due to skin nerve damage ***(Perkins et al., 2009)*.**

It can also cause serious complications such as hemorrhage, femoral artery injury, DVT or pulmonary embolism ***(Critchley et al., 1997)*.**

Venous stripping is typically performed under general or conduction anesthesia. It requires hospitalization, and the usual recovery period, before the patient is fit to work, is approximately 4 weeks ***(Wright et al., 2006)*.**

Despite the theoretically correct assumptions, this conventional surgery has turned out to be a non-radical one. It is linked to a high long-term recurrence rate, reaching even 60–80% ***(Fischer et al., 2001)*.**

Sclerotherapy as the first endovenous chemical procedure also has a history of almost 100 years; however, standardization of the procedure at least since the introduction of various sclerosing foams and its widespread unregulated use are still unsolved problems today. The demand of cosmetically superior, less invasive, and more successful treatment modalities has led to the introduction of minimally invasive techniques. The essentials of these techniques are that there is no need of spinal or general anesthesia and that the recurrence rate of the thermal techniques is much lower than that of surgery. These techniques were introduced only one decade ago and radically changed the treatment of varicose veins ***(van den Bose et al., 2009)*.**

Endovenous thermal ablation (EVTA) therapies have become the most frequently used type of therapy for saphenous varicose veins, in particular, in countries where Reimbursement of the procedure has been introduced. The thermal endovenous techniques are endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and endovenous steam ablation (EVSA). Immediately thereafter EVLA was developed, it became soon the most frequently used EVTA method around the world ***(Goldman et al., 2000)*.**

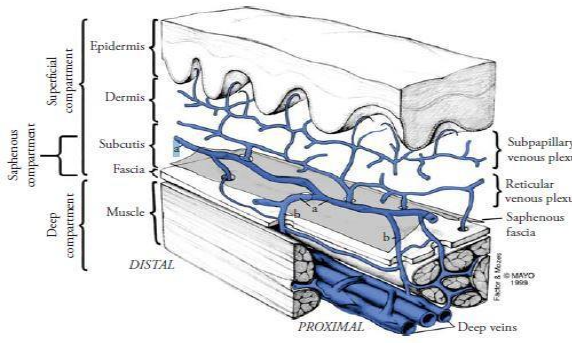
The first results of using water steam for thermal ablation were published in 2009. It was the third method to use high temperature in varicose vein treatment. The steam vein sclerosis (SVS) system, as is the proper name of the technique, consists of a steam generator, an adapter and a compressor ***(Milleret et al., 2009)*.**

Surgical anatomy of lower limb venous system

Thorough knowledge of the fascial compartments of the leg is a prerequisite of understanding the relationship between superficial and deep veins. The fascia surrounding the calf and thigh muscles separates two compartments: the superficial compartment, consisting of all tissues between the skin and the fascia, and the deep compartment, which include all tissues between the fascia and the bones (see Figure 1) **(Geza and peter, 2014).**

The veins of the lower extremity are classified according to their relationship to the muscular fascia and are located in either the superficial or deep compartment .The venous system of the lower extremities includes the deep veins, which lie beneath the muscular fascia and drain the lower extremity muscles; the superficial veins ,which are above the deep fascia and drain the cutaneous microcirculation; and the perforating veins that penetrate the muscular fascia and connect the superficial and deep veins. Communicating veins connect veins within the same system (i.e., deep to deep, superficial to superficial).**(Mark H. Meissner, 2005).**

The saphenous veins are covered by a fibrous sheath, the saphenous fascia The saphenous fascia is thinner than the deep fascia and it is more pronounced in the upper-mid thigh, than more distally. The space between the saphenous and muscular deep fascia is the saphenous compartment. The saphenous compartment is a sub-compartment of the superficial compartment **(Geza and peter, 2014).**



Figure(1) : Relationship between the fascia and veins of the lower extremity. The fascia covers the muscle and separates the deep from the superficial compartment. Superficial veins (a) drain the sub-papillary and reticular venous plexuses, and are connected to deep veins through perforating veins(b). The saphenous fascia invests the saphenous vein. The saphenous compartment is a sub compartment of the superficial compartment **(Geza and peter, 2014).**

1)superficial veins of the lower limb:

The principal named superficial veins are the long and short saphenous veins **(Oguzkurt and Levent, 2012).**

The superficially located vein network of the lower extremities is the most poorly supported and is the source of the earliest subcutaneous varicosities **(Maresa et al., 2013).**

- ***<u>The long saphenous vein</u>*** **:**

Of greatest concern to the physician treating venous problems in the lower extremity is the greater saphenous vein .The term saphenous is derived from the Greek word for “visible" **(D Kachlik et al., 2010).**

The great saphenous vein is the longest vein in the body. It originates from the confluence of the dorsal foot veins on the medial side of the dorsal vein loop and runs consistently along the front of the medial malleolus where it can be seen or felt when standing (Fig. 2).It continues medial to the edge of the tibia up to the knee. At first, it runs in a slightly posterior position, but at about a hand’s-breadth below the knee, it curves further posterior behind the medial femoral condyle in its course along the thigh, it returns to amore ventral position reaching the inner third of the groin where it drains into the femoral vein (Fig 2) Throughout its course, it rests on the muscle or deep fascia. It lies deep to the arch of the saphenous fascia (Fig 3).At its upper end, the great saphenous vein drains into the common femoral vein at the sapheno-femoral junction . Here, it curves down towards the deeper femoral vein where its path has been described as the “ Crosse ” which is French for a bishop‟ s crook. The junction is located in the groin and is always distal of the inguinal ligament **(Alberto Caggiati et al., 2014)**

It has from 10 to 20 valves, which are numerous in the leg than in the thigh **(Carl, 2014).** The most important valves are present at the termination of the vein into femoral vein **(McMinn, 1994).**

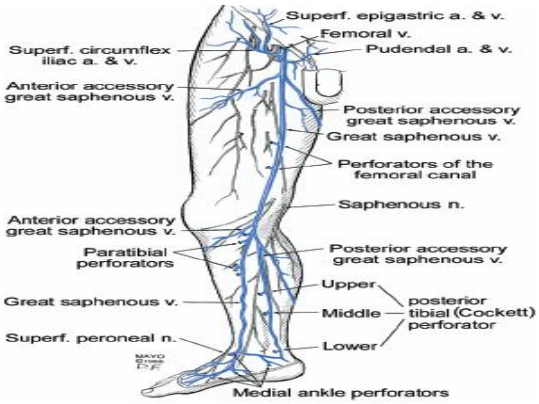


Figure (2) Superficial and perforating veins of the leg (Mozes & Gloviczki; 2004)

Figure (3) Deep veins (Mozes & Gloviczki; 2004)

The accessory long saphenous veins are frequently present and run parallel to the long saphenous vein. Both in the thigh and in the leg they lie anterior, posterior, or superficial to the main trunk .The posterior accessory long saphenous of the leg (Leonardo's vein or posterior arch vein) is a common tributary, it begins posterior to the medial malleolus , ascends on the postero-medial aspect of the calf, and joins the long saphenous vein distal to the knee. The anterior accessory long saphenous of the leg drains the anterior aspect of the leg below the knee .The posterior accessory long saphenous of the thigh, if present drains the medial and posterior thigh. The anterior accessory long saphenous vein of the thigh collects blood from the anterior and lateral side of the thigh. The anterior and posterior long saphenous veins join the long saphenous vein just before it ends at the confluence of superficial inguinal veins (sapheno-femoral junction) **(Fowler et al., 2012).**

- **<u>Tributaries of the long saphenous vein:</u>**

At the ankle the long saphenous vein drains the sole by medial marginal veins **(J. F. Uhl and C. Gillot, 2012).**

In the leg it often connects with short saphenous vein and with deep veins via perforating veins. Just distal to the knee it usually receives three large tributaries; from the front of the leg, from the tibial malleolar region (connecting with some of perforating veins) and from the calf (communicating with the short saphenous vein) **(Da Silva et al., 2017).**

In the thigh the long saphenous vein receives many tributaries. Some open independently; while others converge to form large named channels then frequently pass towards the basal half of the femoral triangle before joining the long saphenous near its termination. These may be grouped as follows: one or more large postero-medial tributaries, one or more antero-lateral tributaries ,four or more peri-inguinal veins .The postero-medial vein of the thigh is large and sometimes doubles drains a large superficial region indicated by its name: it has radiological significance. One of its lower radicals is often continuous with the short saphenous vein. The postero medial vein is sometimes named the term accessory saphenous vein; through some restrict the term accessory to a lower (more distal) postero medial tributary when two (or more) are present (fig. 4) **(Levent, 2012).**

Another large vessel, the antero-lateral vein of the thigh (anterior femoral cutaneous vein), usually commences from an anterior network of veins in the distal thigh and crosses the apex and distal half of the femoral triangle to reach the long saphenous vein. As the latter traverses the saphenous opening, it become joined by the superficial epigastric, superficial circumflex iliac and superficial external pudendal veins. Their mode of union varies **(Fowler et al., 2012).**

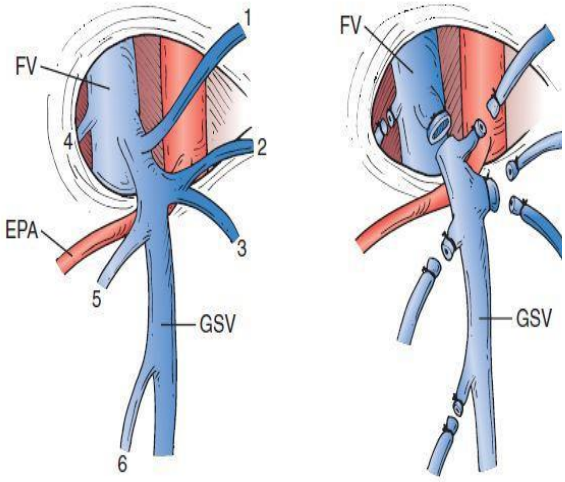


Figure (4) **To the left** The most common arrangement of tributary veins at the saphenofemoral junction. The external pudendal artery (EPA) usually runs between the great saphenous vein(GSV) and the femoral vein (FV), but it may pass above the GSV and is then more susceptible to injury during dissection.1, Inferior epigastric vein; 2, superficial circumflex iliac vein; 3,lateral accessory saphenous vein; 4, deep external pudendal vein; 5, superficial external pudendal vein; 6, medial accessory saphenous vein.
To the right , All vessels must be individually divided and ligated to prevent recurrence. If no stripping of the GSV is to be performed, the proximal 5 to 10 cm of the GSV should be resected. **(Mark and Thomas, 2014)** ***Sapheno-femoral junction (SFJ)***

In this region, the GSV merges into the femoral vein. The region is delineated proximally by the supra saphenic valve and distally by the pre terminal valve of the GSV and the infra-saphenic valve of the common femoral vein (Fig.4) Between the terminal (0 – 1.3cm before the confluence into the femoral vein) and pre terminal vein (0.4 – 8.7cm before the confluence into the femoral vein) of the GSV the superficial circumflex iliac vein, superficial epigastric vein, external pudendal veins (superficial and deep), and/or the anterior accessory saphenous vein can join in a star shape. It must be stressed that this anatomical configuration presents a great deal of variability; for example, the junction location of the veins listed above can be more proximal or distal to the terminal and pre terminal valves. These veins joining the GSV are of clinical relevance because they can be the origin of reflux in the GSV when there is terminal valve sufficiency. On the other hand they can also convey the reflux distally despite preterminal valve sufficiency **(L. Spinedi et al., 2016).**

- ***Small or Short Saphenous System***

The course of the small saphenous vein (SSV) is quite consistent, running along the posterior aspect of the calf. The SSV originates via the lateral marginal branch of the dorsal venous arch and passes anterior to the lateral malleolus. It runs in a dorsal midline subcutaneous plane along the posterior calf and enters the fascia between the heads of the gastrocnemius muscle (Fig.5) .In most cases the SSV enters the deep system approximately 5 cm cephalic to the knee crease by draining into the popliteal vein. In 22 % of cases, however, the SSV continues above the knee, terminating in the sapheno-femoral junction (SFJ)..In the caudal two-thirds of the SSV, the sural nerve is in close approximation to the vein, a clinically relevant issue in cases of SSV ablations where the thermal energy used to ablate the vein can lead to nerve damage and disabling neuropathic pain in some patients **(Brian and David, 2014).**

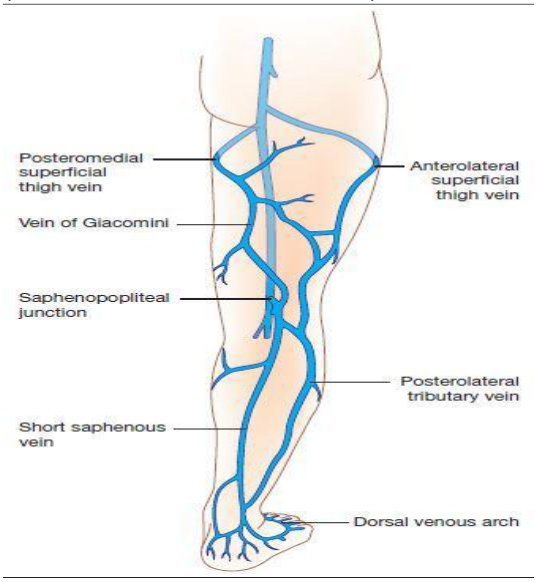


Figure (5) Posterior view of the leg, showing the SSV and its major Branches (Girish and Robert, 2011).

❖ ***Perforating Veins of the Great Saphenous Vein:***

Perforating veins are veins which connect the superficial veins to the deep veins. The great saphenous vein connects with the deep vein through the sapheno-femoral junction as well via a series of perforating veins along its course .These are divided into direct and indirect perforating veins:
Direct perforating veins are those which connect the superficial vein system ,principally the saphenous trunks or their important tributaries, directly with the deep veins. Indirect perforating veins are those which first connect the saphenous trunk veins with muscle veins which only later in their course join the deep veins. The most commonly found muscle veins are the gastrocnemius vein and the soleus vein .Most perforating veins do not join the saphenous trunks directly after they pierce the fascia .Instead, they connect first to saphenous tributaries .However, the perforating veins of the adductor canal in the thigh and the para-tibial perforating veins in the proximal lower leg usually join the below-knee great saphenous vein directly **(Alberto Caggiati et al., 2014).**

2) Deep venous system in the lower leg:

We distinguish between the medial and lateral gastrocnemius muscle veins, the soleus muscle veins (all veins between the gastrocnemius muscles and the deep veins), as well as the fibular vein and the anterior and posterior tibial veins, which are usually paired in the popliteal fossa. These veins join together to become the popliteal vein, which can be doubled in 5 % of cases. The continuation proximally at the height of the adductor canal is called the femoral vein; in the past, it was called the superficial femoral vein. There may be double veins in approximately one-third of cases, and together with the deep femoral vein creates the common femoral vein in the groin. Just proximally to this confluence the great saphenous vein joins the common femoral vein. Using ultrasound, this region is summarized by a "Mickey Mouse" sign **(L. Spinedi et al., 2016).**

PATHOPHYSIOLOGY

Hippocrates was the first to deal with the pathogenesis and epidemiology of varicose disease when he affirmed that varicose veins were more frequent in Scythians due to the prolonged time spent on the horseback with the legs hanging down. In 1514, Marianus Sanctus noted that varicose veins were more frequent after pregnancy and in longtime standing peoples ("...standing too much before kings..."). In 1545, AmbroiseParé related varicose veins to pregnancy and long travelling and affirmed that they are more frequent in melancholic subjects ***(Caggiata and Allegra, 2007).***

Ten years later, Jean Fernel (1554), Professor of Medicine at Paris, stated that varicose veins can develop after an effort or a trauma: "... the varix comes also from a blow, from a contusion, from an effort..." Virchow (1846) was the first to point out the hereditary tendency to varicose veins. Finally, the rare syndrome due to congenital absence of venous valves was first reported by Josephus Luke in 1941 ***(Caggiata and Allegra, 2007).***

Varicose veins are a common disorder affecting 15-30% of western populations, however, despite their prevalence; the etiology of varicose veins remains poorly understood. Histological studies confirm that varicose veins contain abnormalities in the vein wall, including changes in the vessel intima, connective tissue and smooth muscle ***(Elsharawy et al., 2007).***

A dysfunctional venous system follows injury to vein walls and venous valves. This injury is largely due to inflammation, an acquired phenomenon ***(Schmid-Schönbein et al., 2001).***

Factors, which are not acquired, also enter into such injury. These include heredity, obesity, female gender, pregnancy, and a standing occupation in women. Vein wall injury allows the vein to elongate and dilate thus producing the visual manifestations of varicose veins. An increase in vein diameter is one cause of valve dysfunction that results in reflux ***(Bergan and Pascarella, 2007).***

The effect of persistent reflux through axial veins is a chronic increase in distal venous pressure. This venous pressure increases as one proceeds from the inguinal ligament past the knee to the ankle. Prolonged venous hypertension initiates a cascade of pathologic events. These manifest