

EVALUATION OF FOAM SCLEROTHERAPY FOR TREATMENT OF VARICOSE VEINS

Thesis

**Submitted in partial fulfillment of
M.D. degree in General Surgery**

By

Ahmed Aly Radwan

M.B.,B.Ch.,M.Sc.

**Assistant lecturer,General Surgery
National Research Center**

Supervisors

Prof. Dr. Hasan Ahmed Soliman

**Prof. of General and Vascular Surgery
Faculty of medicine
Cairo university**

Prof. Dr. Hesham Ahmed Abo Eisha

**Prof. of General Surgery
Faculty of medicine
Cairo university**

Prof. Dr. Usama Saeed Emam

**Prof. of General and Vascular Surgery
Faculty of medicine
Bani Swef University**

Prof. Dr. Osama Mahmoud Azmy

**Assistant Prof. of Gynecology and obstetrics
National Research Center**

**Department of Surgery
Cairo University**

2009

بسم الله الرحمن الرحيم

" فأما الزبد فيذهب جفاء و أما ما ينفع
الناس فيمكث فى الأرض"

صدق الله العظيم

ACKNOWLEDGEMENT

*I would like to express my sincere gratitude to Prof. Dr. **HASAN AHMED SOLIMAN**; professor of Vascular surgery who suggested the idea of this thesis , for his unfailing encouragement, and stimulating advices.*

*I am deeply indebted to Prof. Dr. **ALAA SHARABEE**; Head of Vascular surgery unit, Alazhar University, who taught me the technique for foam preparation honestly and faithfully.*

*I would also like to gratefully acknowledge the sincere contribution of Prof. Dr. **HESHAM AHMED ABO ESHA**, professor of General and Vascular surgery, for his kind supervision and valuable discussions.*

*I really appreciate the meticulous, sincere guidance, and valuable help of Prof. Dr. **USAMA SAEED EMAM**, professor of General and Vascular surgery, who supervised me in every step to produce this work, without his skillful contribution, this work would not have been completed. Thank you sir for your continuous and outstanding support.*

*I would like to thank Prof. Dr. **OSAMA MAHMOUD AZMY**, Prof. of Gynecology and Obstetrics, Head of our Department at the National Research Center, for his continuous encouragement and support throughout the whole work.*

*Finally , I would like to express my thanks to all the staff members of our surgical department especially my colleague **Amr Bahaey**, for their support, cooperation and encouragement.*

CONTENTS

	Page
INTRODUCTION AND AIM OF WORK.....	9
REVIEW OF LITERATURE:	
* ANATOMY OF THE VEINS OF LOWER LIMB.....	10
▪ <u>Developmental Anatomy Of The Lower Limb Veins</u>	10
▪ <u>Gross Anatomy Of The Lower Limb Veins</u>	10
▪ <u>Microanatomy Of The Veins</u>	27
* PHYSIOLOGY OF THE VENOUS SYSTEM OF THE LOWER LIMB.....	32
▪ <u>Mechanism of Venous Drainage</u>	33
▪ <u>Functions of veins</u>	34
▪ <u>Function of venous endothelium</u>	37
* PATHOLOGY OF VARICOSE VEINS.....	38
▪ <u>Hypothesis on Aetiology of varicose veins</u>	40
▪ <u>Pathology of Symptomatology</u>	43
* CLINICAL PICTURE OF VARICOSE VEINS.....	45
▪ <u>Uncomplicated Varicose Veins</u>	45
▪ <u>Complicated Varicose Veins</u>	46
* Diagnosis and Recent Investigations.....	49
▪ <u>Clinical Diagnosis</u>	49
▪ <u>Investigations of Varicose Veins</u>	53
* TREATMENT OF VARICOSE VEINS.....	56
▪ <u>Conservative measures</u>	56
▪ <u>Elasto-compressive therapy and treatment by posture</u> ...	57
▪ <u>The Surgical Management of Primary Varicose Veins</u>	61
▪ <u>Traditional Liquid Sclerotherapy</u>	64
▪ <u>Laser Therapy</u>	66
▪ <u>Endovenous laser</u>	66
▪ <u>Radiofrequency</u>	67
▪ <u>Foam Sclerotherapy</u>	67
✓ Definition	67
✓ Introduction.....	68
✓ History of sclerosing foam.....	69
✓ Mechanism of action of foam.....	76
✓ Pathology of post injection thrombus.....	77
✓ Agents most commonly used.....	84
✓ Indications of foam sclerotherapy.....	86
✓ Contraindications of foam sclerotherapy.....	88
✓ Complications of foam sclerotherapy.....	90
✓ Advantages of injection sclerotherapy.....	93
PATIENTS AND METHODS.....	97

RESULTS.....	100
DISCUSSION.....	110
SUMMARY AND CONCLUSIONS.....	115
CASES.....	117
REFERENCES.....	123
ARABIC SUMMARY.....	137

List of FIGURES

	Page
<u>Figure 1:</u> The venous system of the lower limb.....	11
<u>Figure 2:</u> Anatomy of the long Saphenous Vein.....	13
<u>Figure 3:</u> Anatomy of the right saphenofemoral junction.....	14
<u>Figure 4:</u> Small saphenous vein and its tributaries.....	17
<u>Figure 5:</u> Deep venous system of the left lower limb.....	19
<u>Figure 6:</u> Valves of the venous trunk.....	23
<u>Figure 7:</u> Sites of the perforators.....	25
<u>Figure 8:</u> A cross section in a vein filled with blood.....	28
<u>Figure 9:</u> Muscle pump effect on venous return.....	35
<u>Figure 10:</u> The air-block technique.....	70
<u>Figure 11:</u> The aspiration technique.....	71
<u>Figure 12:</u> The Mayer-Brucke device.....	72
<u>Figure 13:</u> The low-pressure technique.....	73
<u>Figure 14:</u> Components used in the double-syringe technique.....	75
<u>Figure 15:</u> Double-syringe system (DSS) foam.....	75
<u>Figure 16 :</u> Graphic representation of sex distribution.....	100
<u>Figure17 :</u> Graphic representation of age distribution.....	101
<u>Figure 18 :</u> Graphic representation of different complaints.....	102
<u>Figure 19 :</u> Graphic representation of different systems affected.....	103
<u>Figure 20:</u> Three groups vein diameter in both limbs.....	104
<u>Figure 21 :</u> Post injection complications.....	107
<u>Figure 22:</u> Post injection efficacy, duplex evaluation.....	108
<u>Figure 23 :</u> Patient satisfaction in both groups.....	109
<u>Figure 24 :</u> Case of incompetent SFJ with incompetent perforators....	117
<u>Figure 25 :</u> Case of incompetent SFJ.....	118
<u>Figure 26 :</u> Case of incompetent SPJ.....	119
<u>Figure 27 :</u> Case of incompetent SPJ.....	119
<u>Figure 28 :</u> Case of superficial varicosities.....	120
<u>Figure 29 :</u> Case of superficial varicosities.....	120
<u>Figure 30 :</u> Case of venous ulcer.....	121
<u>Figure 31 :</u> Complications.....	122

List of Tables

	Page
<u>Table 1:</u> Overview of elastic stocking gradients.....	59
<u>Table 2:</u> Overview about the contributions to foam sclerotherapy.....	68
<u>Table 3:</u> Sex distribution in both groups of the study.....	100
<u>Table 4 :</u> Age distribution in both groups of the study.....	101
<u>Table 5 :</u> Study of the different complaints in both groups.....	102
<u>Table 6:</u> Distribution of the venous system affected in both groups...	103
<u>Table 7:</u> Different vein diameters in both groups.....	104
<u>Table 8:</u> Number of sessions for each group of vein diameter.....	105
<u>Table 9:</u> Number of sessions in vein diameter(1-2)mm.....	105
<u>Table 10:</u> Number of sessions in vein diameter(2-4)mm.....	105
<u>Table 11:</u> Number of sessions in vein diameter(4-8)mm.....	105
<u>Table 12:</u> Post injection complications.....	106
<u>Table 13:</u> Post injection efficacy, duplex evaluation after one year....	108
<u>Table 14:</u> Patient satisfaction in both groups.....	109

List of Abbreviations

AVP.....	Ambulatory venous pressure
CO ₂	Carbon dioxide
CVI.....	Chronic venous insufficiency
DSS.....	Double syringe system
DVT.....	Deep venous thrombosis
FDA.....	Food and drug administration
HPD.....	Hydroxypolyethoxidodecaine
mm.....	Millimeter
ml.....	Milliliter
mmHg.....	Millimetermercury
NSAID.....	Non steroidal anti-inflammatory drugs
PDA.....	Product development authority
POL.....	Polidocanol
SFJ.....	Saphenofemoral junction
SPJ.....	Saphenopopliteal junction
STD.....	Sodium tetradecyl sulfate
STS.....	Sodium tetradecyl sulphate
μ.....	Micron

ABSTRACT

The use of foamed sclerosants in phlebology is not new. Nevertheless, the worldwide use of this treatment was " relaunched " only a few years ago. This first start with refrence to ***Stuard McAusland – 1939***, who proposed the use of "froth" in telangiectasia. The foam he prepared was obtained by simply shaking the rubber-capped bottle that was filled with sodium morrhuate, and then the froth was aspirated into a syringe. He treated spider veins or telangiectasia, where he noticed that the" veins suddenly got pink, sometimes retracted and almost disappeared at once".

Key words:

***Varicose Veins – Sclerotherapy - Foam Sclerotherapy – Foam -
Polidocanol.***

INTRODUCTION AND AIM OF WORK

Venous disorders are very common and especially affect the lower limb. Twenty per cent of the population suffer with varicose veins and two per cent have skin changes which may precede venous ulceration. At any one time two hundred thousands people in the UK have active venous ulceration. In England, The provision of wound care and bandaging costs the National Health Service six hundred millions pound per annum (*Scurr et al., 2000*).

The use of foamed sclerosants in phlebology is not new. Nevertheless, the worldwide use of this treatment was " relaunched " only a few years ago. This first start with refrence to *Stuard McAusland – 1939*, who proposed the use of "froth" in telangiectasia. The foam he prepared was obtained by simply shaking the rubber-capped bottle that was filled with sodium morrhuate, and then the froth was aspirated into a syringe. He treated spider veins or telangiectasia, where he noticed that the" veins suddenly got pink, sometimes retracted and almost disappeared at once".

This work is designed and planned to study Fifty cases of leg varicose veins will be classified into two groups. Group(A),Where the traditional liquid sclerotherapy technique will be applied on twenty-five cases, Group (B),Where the foam sclertherapy technique will be applied on twenty-five cases .Each group will be followed up for the results after injection to identify the effect of each technique on the varicosities and to detect any complications for one year.

The aim of this study is to Estimate the value of foam sclerotherapy among other modalities of treatment, Identifying advantage and disadvantage, Trying to standardize the new *Tessari Technique*, Stand on the precise indications , contraindications, Evaluation of the safety and efficacy of the different doses and concentration of the foam per injection.

ANATOMY OF THE VEINS OF LOWER LIMB

▪ **Developmental Anatomy Of The Lower Limb Veins:**

By the fourth week of the intrauterine fetal life, a swelling of the lateral embryonic body wall forms the limb buds. These buds are highly vascularized, the arteries being axial and veins are marginal. The anterior marginal veins are pre-axial and the posterior marginal veins are post-axial; both empty into the posterior cardinal vein (*Beesley & Johnston, 1939*).

In adult life, the pre-axial vein of the lower limb becomes *the great or long saphenous vein*, which more proximally gives rise to the proximal femoral vein and the external iliac vein. The post-axial vein becomes the *lesser or the short saphenous vein*, which more proximally gives rise to the popliteal vein, the inferior gluteal vein and the internal iliac vein (*Davies & Davies, 1964*).

▪ **Gross Anatomy Of The Lower Limb Veins:**

The venous system of the lower limb consists of three main groups (**Figure 1**):

- 1- The superficial group.
- 2- The deep group.
- 3- The communicating and/or perforating group.

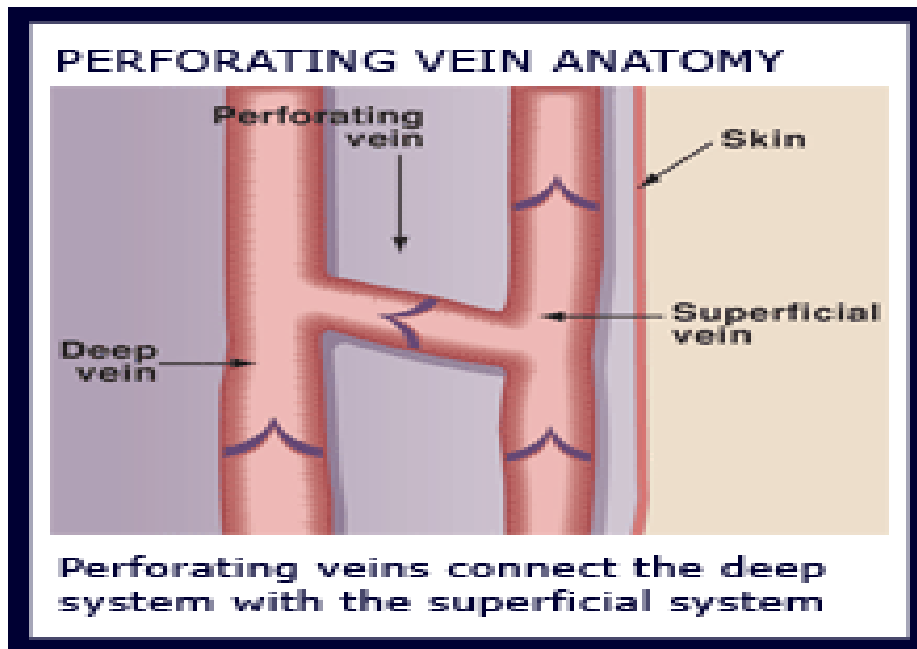


figure 1: The venous system of the lower limb (*Weiss, 2002*)

1. The Superficial Veins Of The Lower Limb:

These superficial veins lie in the fat between the skin and the deep fascia, being closer to the latter (*Dodd & Cockett, 1956*). They carry about 10-15% of the venous drainage of the lower limbs. They can be observed in three strata:

- 1- The thin-walled subcuticular vessels or venules, which form a considerable plexus under the skin.
- 2- These venules join to form a network of larger subcutaneous veins, which form most of the prominent superficial varices following incompetence of the main trunks.
- 3- The main trunks of the long and short saphenous veins which lie on the deep fascia (*Shepnered, 1966*).

In the proximal half of the thigh, where the subcutaneous tissue consists of a superficial fatty layer (Camper's fascia) and deep membranous layer (Scarpa's fascia), the major venous channels (great saphenous vein) are found deep to the Scarpa's fascia (*Thomson, 1994*).

The superficial venous drainage of the lower limb consists of:

A- Venous drainage from the toes and foot:

The dorsal digital veins receive, in the clefts between the toes, communication from the plantar digital veins, then they join to form the dorsal metatarsal veins, which unite across the proximal part of the metatarsal bones in a dorsal venous arch. Proximal to the dorsal venous arch, there is an irregular dorsal venous network on the front of the leg. At the sides of the foot, this network communicates with a medial and a lateral marginal veins, both are formed mainly by the union of veins from the superficial part of the sole of the foot (*Davies & Davies, 1964*).

B- The long saphenous vein (syn. Great, large, internal saphenous vein, saphena magna):

The long saphenous vein is the *longest* vein in the body. It is formed as a continuation of the medial marginal vein from the dorsal arch on the dorsum of the foot. Then it runs upwards 1 to 1.5 inches in front of the medial malleolus of the tibia lying in the groove between the anterior border of the medial malleolus and the tendon of the tibialis anterior muscle. It ascends obliquely upwards and backwards over the medial surface of the leg till it reaches the medial condyle of the femur over the posteromedial aspect of the knee. Then it climbs slightly forwards crossing the anteromedial aspect of the thigh till it pierces the cribriform fascia to reach the foramen ovale to join the common femoral vein at the groin (*Dodd & Cockett, 1993*).

A reliable surface marking of the saphenofemoral junction is 1.0 to 1.5 inches below and laterals to the pubic tubercle. This junction may be below this point in thin people (*Hobbs, 1994*).

On palpating this vein in relation to the knee, it is to be found just posterior to the transverse axis of the joint (*Dodd & Cockett, 1956*).

Yet, as a rule for veins, this course is only for anatomical description, and variations do exist. *Blomquist (1968)* showed the following variations:

- Low termination of the long saphenous vein, where the proximal portion of it, proximal to the last perforator is obliterated and the perforator replaces the vein and both superficial epigastric and external pudendal veins drain directly into the femoral vein, while the superficial circumflex iliac terminates at the long saphenous vein.
- Accessory saphenous vein may accompany the course of the long saphenous vein.
- In one third of the population, the long saphenous vein is double barrelled.

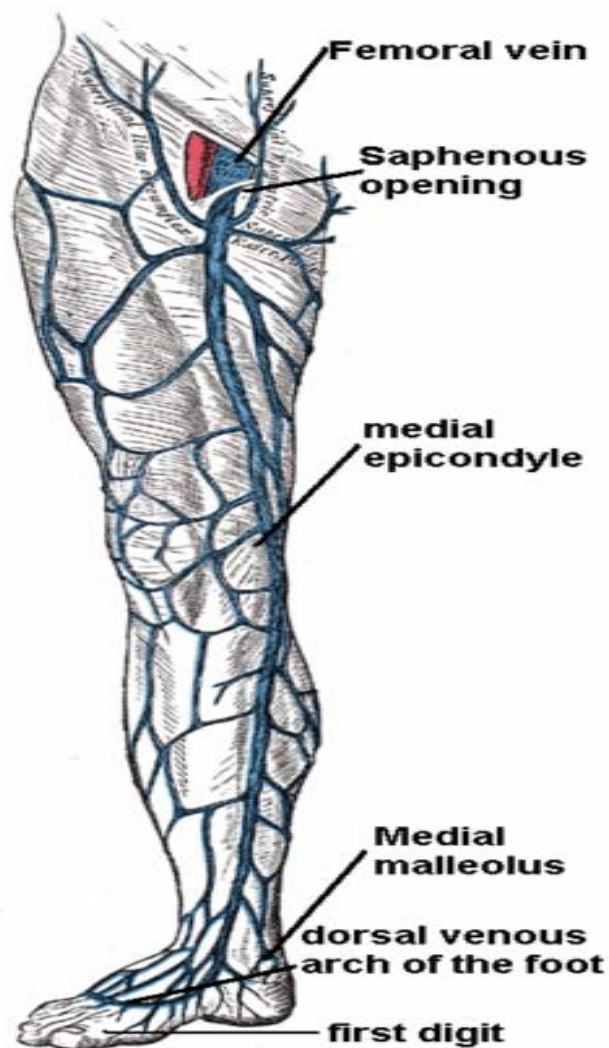


Figure2: Anatomy of the long Saphenous Vein (*Jagger , 1994*)

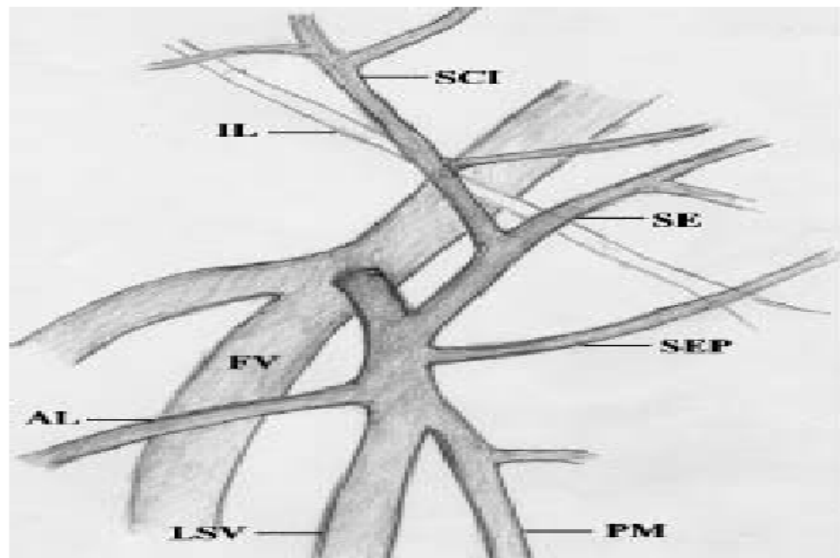


figure 3: Anatomy of the right saphenofemoral junction: **AL**; anterolateral tributary, **FV**; femoral vein, **IL**; inguinal ligament, **PM**; posteromedial tributary, **SCI**; superficial circumflex iliac vein, **SE**; inferior superficial epigastric vein, **SEP**; superficial external pudendal vein. (*Adhikari et al., 2000*)

Relationship of surgical importance:

The saphenous nerve in the leg lies close to the long saphenous vein. The nerve approaches the vein below the knee after piercing the fibromuscular roof of the adductor canal. The nerve becomes close to the vein in the lower two thirds of the leg and bifurcates above the ankle over the vein. This nerve may be injured during stripping (*Dodd & Cockett, 1993*).

Tributaries of the long saphenous vein :

According to *Moosman & Hartwell, (1964)*, the long saphenous vein has many tributaries as follows:

- a) The posterior arch vein is a large constant vessel which arises from a series of small venous arches connecting the medial ankle perforating veins. These venous arcades receive the delicate venules which drain the skin of the ankle and heel. It is these small vessels which become dilated in venous incompetence and give rise to the hemangiomatous appearance which obliterates the hollow behind the malleolus