Endovenous Laser Ablation of Varicose Veins 10 years after: Past, Present & Future

Selected Papers

IUA World Congress
Buenos Aires - Argentina
April 21 - 25th, 2010

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FOREWORD

As President of the XXIV World Congress of the International Union of Angiology in Buenos Aires, my primary goal has been to bring contribut of interest and value oriented not only as a continuing clinical update, but also to allow innovation. This Book is devoted to discuss the new treatment of chronic venous disease (CVD) by endovenous laser ablation (EVLA). The need for ongoing attention to this optimal and new standard of care for such as large number of patients derives from the level of satisfaction reported by the patients themselves.

This "update" issue is comprised of three parts. The editorial by Giovanni B. Agus, founder of the International Endovenous laser Working Group (IEWG), confronts the change of paradigm in the treatment of varicose veins in the last decade "10 years after: Past, present & future". At the heart of the supplement, having being sent numerous contributions to the Congress on EVLA, those accepted and collected in different sessions, have been selected for this issue. Those authors that have accepted the invitation of sending a short paper for a broader discussion at the congress are present. The selection has allowed for addressing most issues at stake in EVLA: new technologies in wavelengths and in fibers; clinical indications of treatment of the great and small saphena, class C6 of ulcers; results of experiences in many parts of the world; and last but not least, treatment safety.

It concludes with interesting final remarks from John Mauriello, who points out that "in just six years not only has surgery dropped from 93% to 5% of the number of procedures performed but the total number of procedures has tripled. EVLA is clearly the most performed treatment for varicose veins in the USA and now accounts for more than 70% of all procedures".

EVLA appears today as a unifying technique for many of the members of the IUA commited to curing CVD, vascular surgeons, angiologists, dermatologists, and this is also an important result.

Prof. Robert Simkin
Congress IUA 2010 President

EDITORIAL

Endovenous Laser Ablation of Varicose Veins 10 years after: Past, Present & Future

The changing paradigm. The past

According to Thomas Kuhn, as well known, "a paradigm is what members of a scientific community, and they alone, share". Once a paradigm shift is complete, in our case a phlebologist cannot for example posit the possibility that other than long reflux always causes varicose veins or that the only saphenofemoral junction is the key of the problem, so that we have "to do only crossectomy and stripping, and all the other things are dangerous!". Progress in the treatment of varicose veins has today focused on the endovascular treatments welcomed by both physicians and patients because of less invasiveness, less recurrence, less collateral effects.

From Buenos Aires to Buenos Aires. Ten years ago an Italian paper was published in Buenos Aires about the use of the endovenous laser ablation (EVLA) for varicose veins (1), and now in Buenos Aires we have the opportunity to celebrate ten years of experience of EVLA. Generally, the beginning of EVLA is quoted to the Spanish Carlos Bonè (2), even though in the UIP World Congress in 1986 in Strasbourg another Italian experience was presented (3). Finally, EVLA was approved by the USA FDA in January 2002.

The results of EVLA. The present

In 2004 Michel Perrin published in Phlébologie, the first literature review and the results on chronic venous insufficiency (CVI) endovascular treatments either by means of radiofrequencies (RF) as well as with EVLA. Middle term results for both techniques were considered effective and less invasive compared to stripping. Furthermore, he was correct when stating that laser treatments were not all the same and therefore not very easily comparable (4).

Peter Gloviczki, to stay successful in the long term, also-recommended an appropriate use of new techniques on certification, quality control, and education (5). With time and because of the high interest in that laser technology has grown, several reviews have treated this argument, among which the current most representative meta-analysis is by Van den Bos and al. (6).

Personally, we have compared our results according to three different phases of our experience: the first one with a randomized trial of laser treatment versus stripping; a series of studies in progress on various aspects; up to the experience known as International Endovenous-laser Working Group (IEWG) (7, 8). From the literature review it comes out than only few people declare to follow a precise protocol step by step, at the base of their personal experience. The effectiveness of the treatment merges out clearly, but from congress contributions and debates, some critical aspects nonetheless emerge, over possible collateral effects or complications. Firstly, there has been no common decision on the method name (ELT, EVL, EVLA, EVTA, IVA, besides commercial names). It is time to select one abbreviation for endovenous laser treatment (thermal ablation) for the cultural implications as far as image towards patients, media and health organization is concerned. From the clinical point of view we assist to unfitting indications, while they should be the same as it is for stripping for about

50% of CVI surgery. It is recommended to inform on wrong hemodynamic indications (preservable saphenous vein always useful as possible graft). Significant and exclusive index concerning the choice of the appropriate surgery method to be performed on patient, such as symptoms, signs, severity score index, patient and surgeon satisfaction, quality of life survey and on the other side the instrumental mapping with Duplex, could alter the result in the long run. Regarding the laser instrumentation, it should be considered that devices may have different wave-lengths in diode employment or Nd:YAG; as well as the insufficient attention to protocols instructions and several do-it-yourselves. More recently it has been opportunely recommended to use reporting standards (9).

Association of proximal vein ligation to great saphenous vein (GSV) laser treatment is very rarely considered necessary. Since the incidence of reported deep venous thrombosis (DVT) and pulmonary embolism (PE) is quite rare among entire groups of experiences, it would appear that GSV ligation, even in selected patients, may be a superfluous gesture (10).

In spite of the initial doubts there is a good possibility to treat the small saphenous vein (SSV) (11). The opportunity to treat stab phlebectomy of collaterals at the same time or deferring is being discussed (12-14). In Italy for patient's preference we prefer contemporary treatment. Results are not very easily comparable: the majority appear well balanced with distance obliteration percentage higher than 90% and significant satisfaction reported by patients, but range goes from enthusiastic (15) to cautious when obtained from Randomized Clinical Trials (RCT) (16). Follow up has now reached 10 years; for many experiences however the necessary time beyond 3-5 years has not been reached. In the meantime, from procedure facts and from various literature experiences, it emerged that specific counter-indications connected to morphology or diameter of the vein to be treated are very few. Therefore the consequent simplicity of the vein catheter procedure and endovascular treatment conduction carried out by the operator show a low procedure difficulty and few perioperative accidents, which on the contrary, without an accurate critical vision of the procedure itself could subsequently invalidate the results at a distance, increase complications in the short term, and damage the image of the endovascular treatment, jeopardising certainty of a centenary surgery.

The GSV is resulting to be the target of CVI treatment more often taken into consideration in the thigh portion, as a result of clinical necessities and hemodynamic evidence, but also due to the risk of damaging the saphenous nerve in its tract of the leg. This neurological risk explains why the SSV is being treated more occasionally with endoluminal procedure. The excellent results on clinical basis and in correlation between the results monitored with Duplex and clinical examination, show several elements which validate the procedure. Postsurgical course is less painful in the endovenous procedure, going back to normal activities is faster and convalescence is shorter. Analysing postsurgical complications, neurological disturb seems frequent after endoluminal treatment, more denounced than described, but gradually disappearing with time. Varicose endoluminal treatment has remarkable advantages compared to classic surgery in terms of improvement of post surgery course and even more on evaluating results in the long term, except for conceptual and practical bad use of the procedure.

Challenges for the EVLA in the future

May be the future is now. Endovascular treatments are today the most preferred solution receiving patient's satisfaction. Once found all comfort and security problem solutions and thanks to improved knowledge on the best power wavelengths to be used, the procedure may really be carried out as outpatient treatment with less risks and side effects or complications. Until now, energies spent involve an uneasy standardization of the connection of the parameters for the various thicknesses (mm) - power (W) - time (msec) - fluency (J/cm²). The last years showed examples of higher dosage (17), lower but longer exposure/T (18), review on behaviours for incomparability (19), but with the new laser wavelengths like diode 1470 nm remarkable effective results and less collateral effects were achieved comparing the results and the effects currently obtained by using higher power and shorter laser wavelengths (World Congress of Union Intérnationale de Phlébologie, Monaco 2009).

It is now time where EVLA (or other acronym) is probably matching its role vs. foam sclerotherapy (20), well combined eventually to other venous surgery (21), and no longer with "the old stripping" (John Bergan).

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Summary

W. Cecchetti

Temperature measurements to improve Endo Laser Vein System ablation with 980 and 1470nm diode lasers

Temperature measurements to improve Endo Laser Vein System ablation with 980 and 1470nm diode lasers

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ABSTRACT

Purpose
We performed a series of in vitro studies with temperature measurements in order to comprehend the complex phenomenology linked the saphena occlusion procedures by endovenous lasers.

Materials and methods
First we graphed the absorption spectra of venous blood and water at the 980 and 1470nm wavelengths. With an experimental device, we simulated what happens on the fiber tip inserted in the vein and immersed in blood. With thin thermocouples placed on micrometric slides, we measured the temperatures in the surroundings of the fibers tips immersed in blood during laser emission. We performed the measurements by simulating the procedures with a 980nm diode laser (ELVeS). The spectra performed on blood and water showed the same high absorption at the 1470nm wavelength, so we simulated the procedures with 1470nm laser (ELVeS) using water instead of blood. With the 1470nm laser, we tested a fiber capable of emitting radiation radially from the fiber axis, in a circular and homogeneous way, named radial fiber.

Results
Radiation absorption of the blood at 980nm, produces the thermal rise in surroundings of the flat fiber tip. In order to obtain the thermal-shrinking effect with optimal occlusion, the vein must heat up to a temperature between 80 °C and 90 °C. We optimized the 980nm laser outputs to obtain optimal shrinking temperatures in the surroundings of the fiber tip (towards the internal side of the vein). With the 1470nm laser, the absorption is much higher than with 980nm, both in blood and in water, so this source turns out more effective and efficient than 980nm. That efficiency induced us to test the 1470nm with the radial fiber, with results beyond our expectations. Actually, we reached the optimal temperatures in the surroundings of the fiber, that in our model corresponds to the internal wall of the vein, with powers of only 3W or 4W CW (continuous wave).

Conclusions
The optimization of the 980nm laser output linked with a flat fiber is capable of giving accurate indications to the operator in terms of efficiency and safety of the EVLA method. The use of 1470nm diode laser opens remarkable possibilities and potentials in EVLA method. From the summary tables a remarkable efficacy of this wavelength can be deducted, that, the use of the radial fibers, can provide venous shrinkage with low emitted power levels and minimal pain for the patients, becoming a real painless laser treatment.

Introduction

The use of lasers for EVLA procedures and the absorption spectra of venous blood and water in the 800-1500nm range, are the key to understand the phenomena related to thermal vein occlusion. In state of the art literature, radio frequency systems VNUS Closure™, used for the thermal occlusion of the saphenous vein, were equipped with intravenous probes with thermocouples. These systems have helped to ascertain that to obtain complete thermal shrinkage of the saphenous vein, the entire wall of the vein has to reach a temperature of about 85 °C (1, 2).

After performing the absorption spectra of water and blood around 980nm (fig. 1), we developed an experimental device (fig. 2), which allowed us to simulate the EVLA procedures. We measured the temperatures at the end of a flat tip fiber immersed in heparinized venous blood, delivering 12W at 980nm (3). Then we performed the absorption spectra of water and heparinized blood around 1470nm (fig. 3-6). We simulated the EVLA procedures with a 1470nm laser linked to a fiber with radial emission at 360 degrees. Since around 1470nm both water and blood have an equal absorption of almost 100%, we measured the temperature at the end of the radial fiber immersed in water. In both simulations we observed the presence of water vapor bubbles (4, 5), fundamental for the success of the method. The 1470 diode laser and radial fiber system has shown a remarkable efficiency, reaching shrinkage temperatures with only 3W, and the formation of vapor bubbles with 6W (6, 7) able to perform the complete occlusion of saphenous vein with minimal pain for the patients.

Materials and methods

1. Experimental device as fig. 2, with: X-Y micrometric slide, 1µm precision, digital thermometer mod. Omega, linked with 220µm thermocouple, precision 0.1°C.
2. Diode Lasers Biolitec, 15W emitting power, 980nm and 1470nm Wavelengths.
3. Optical Fiber AS, quartz, NA 0:37 to 600µ, flat tip.
4. Optical Fiber AS, quartz, NA 0:37 to 600µ, radial tip.

We performed the absorption spectra of heparinized venous blood on an optical path of 1 mm, and water on an optical path of 10 mm (fig. 1a and b). We have developed the experimental device shown in fig. 2, with it we simulated the EVLA treatment with the 980nm laser linked to a 600µm fiber with flat tip, emitting power 12W.
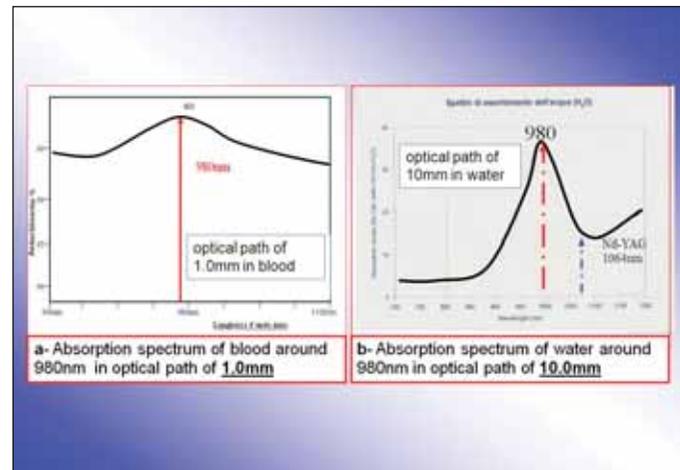

Fig. 1a and b - Absorption spectra of blood and water around 980nm.
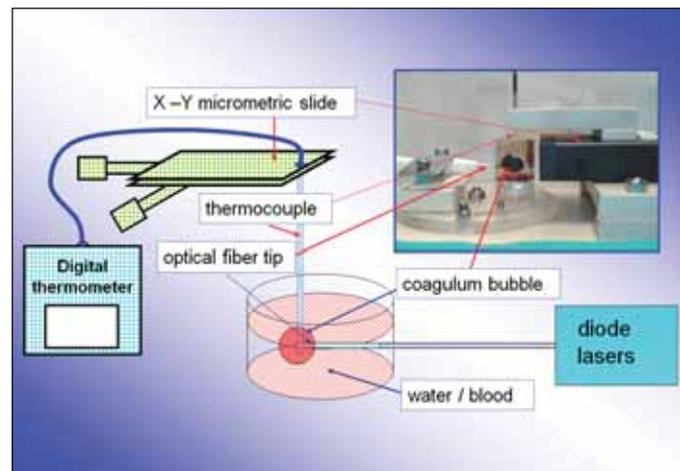

Fig. 2 - Experimental device for the temperature measurements at the distal tip of fibers in the ELVeS procedures simulation.

With a thermocouple linked on micrometer sleds, we performed a measurement series of temperatures around the fiber tip immersed in heparinized blood. With the collected data we constructed the summarizing graphs in fig. 3.

We performed the transmission* spectra of water and blood around 1470nm (fig. 5a, and 5b, optical path 1 mm).

With the experimental device of fig. 2, we simulated the EVLA treatment with 1470nm laser linked to a 600µm fiber with ring radial emission at 360 degrees, with the tip immersed in water. For trials, we used water because at 1470nm* both water and blood have equal absorption, almost 100%. The outline of operation of the radial fiber is shown in fig. 6; to measure the temperatures at its end we had to use a special thermocouple ring, placed at the ring exit of the radiation.

We delivered several power patterns with the 1470nm laser, measured their temperatures and with the collected data we constructed the summary graphs in fig. 7.

Results and discussion

Delivering 12W at 980nm with a flat fiber immersed in venous blood and measuring its temperature, we constructed the graphs of fig. 3, and the pattern of fig. 4 which goes on describing the mechanism of action of thermal occlusion of the saphenous vein. The fiber is immersed in venous blood, which on the optical path of 1mm has an absorption >99.5%, then the first particles of blood in contact with the fiber tip that are irradiated, heats up very fast, loses water, exceeds well over 100 °C and carbonizes. After 10 seconds a coagulum ball forms which transfers the heat to the vein walls. In front of the fiber tip the temperature rises to well over one hundred degrees and the water in the blood becomes vapor bubbles. The coagulum ball and the water vapor bubbles transfer heat to the vein walls, which, around 80-85 °C undergo the occlusive heat shrinkable effect. From the graphs we see that the mechanism of occlusion needs 10-12 seconds to ignite, then the coagulum ball and vapor bubbles formation start, which is fundamental for the heat distribution on the vein walls to reach the 85 °C threshold.

After a few seconds from their formation, the vapor bubbles release heat, condense, and become water molecules dissolved in the blood. The aqueous component of blood (about 90%), acts as a thermostat temperature limiter, so, as long there is water in the blood, carbonization does not and the temperature does not exceed 100 °C.
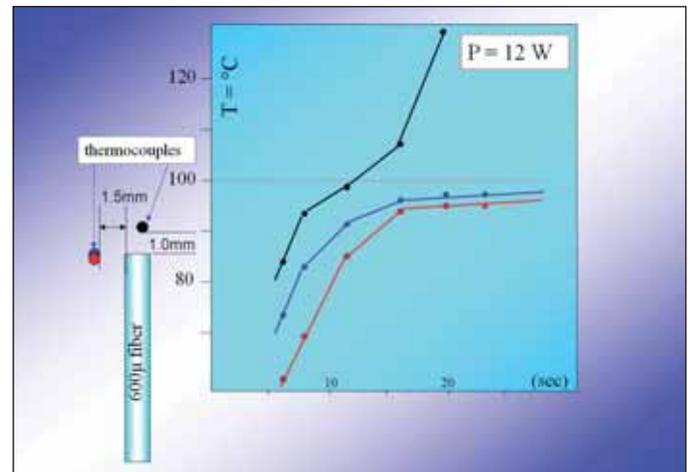

Fig. 3 - Temperature measured at 1mm on the tip and 1.5 mm lateral from the fiber tip with 12W of 980nm diode laser.
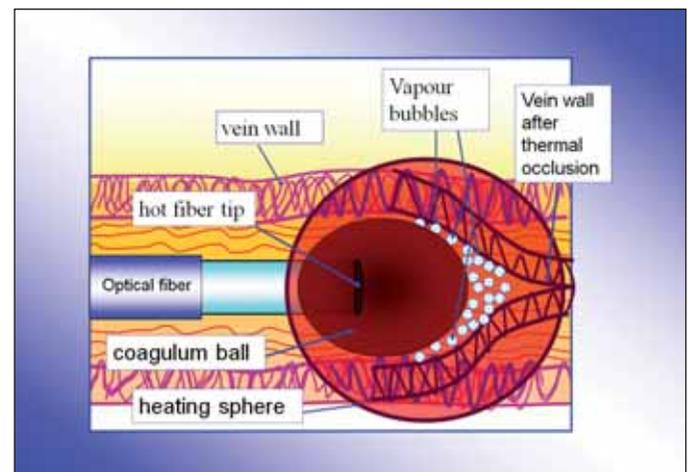
Fig. 4 - Thermal distribution of heating in ELVeS treatments with flat tip fiber linked with 980nm diode laser.

Given the absorption spectra of blood and water around 1470nm, we performed the tests with a new fiber with ring radial emission at 360° immersed in water. The radial fiber projects the radiation directly to the vein walls so it is more efficient than the flat tip fiber: it takes just 3W to reach the temperatures necessary for the thermal vein occlusion.
Over 6W, the boiling point is reached and water vapor bubbles begin to form in the space between the vein wall and the lateral surface of the radial fiber (fig. 8).
Figure 7 shows the trends of measured temperatures, and in fig. 8 the thermal distribution of heating in EVLA treatments with "ring radial fiber" linked with 1470nm diode laser is reported. Thus the 1470 ELVeS system with ring radial fiber, due to the high absorption of blood at 1470nm and the ring radial geometry, optimal for transferring heat to the walls of the vein, with only 3W is capable of occluding the veins with a diameter of up to 7-8 mm. With powers over 7-8W many vapor bubbles are formed on the cylindrical surface of the ring radial fiber migrating toward the vein wall, so we can treat varicose veins with large diameters (>1.0 mm) and with morphologies otherwise altered. Warning: we observed that delivering 16W at 1470nm with ring radial fiber, we achieved the formation of a plasma ring on the emission point of radiation, capable of producing destructive ablation of soft tissue near the radial tip.

Conclusions

The optimization of the 980 nm laser output linked with a flat fiber is capable of giving indications to the operator in terms of efficiency and safety of the EVLA method (3).
The use of 1470 nm diode laser opens remarkable possibilities and potential in EVLA method (6, 7), from the summary plot of fig. 7, a remarkable efficacy of this wavelength can be deducted, that, with the use of the ring radial fibers (fig. 8), can provide venous shrinkage with low emitted power levels and minimal pain for the patients, becoming for a real painless thermal-occlusion laser treatment.
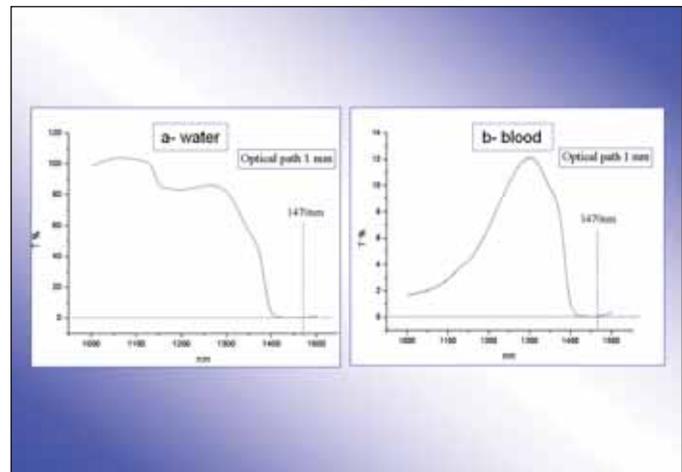
Fig. 5 - Water and blood transmission* spectra around 1470nm
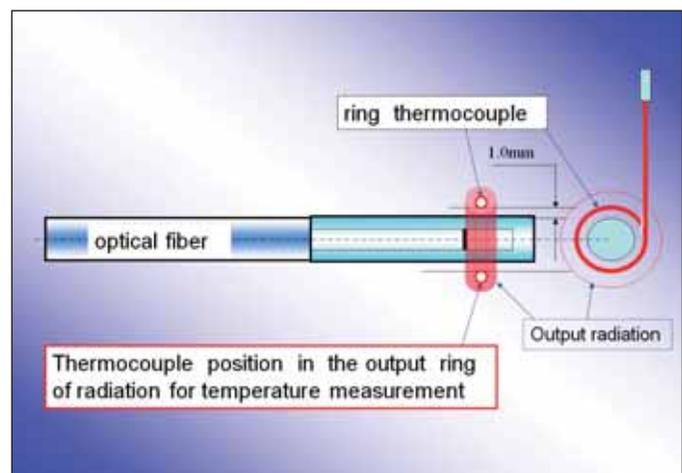
Fig. 6 - 600μm *ring radial fiber* linked with 1470nm diode laser for ELVeS procedures.

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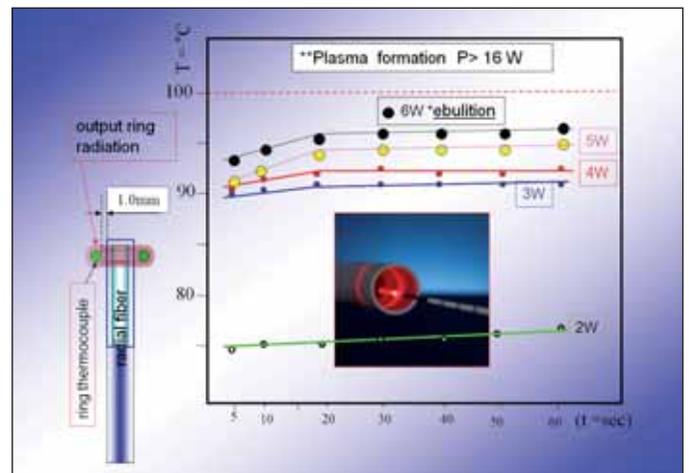
Fig. 7 - Measured temperature at 1.0 mm laterally of *ring radial fiber*.
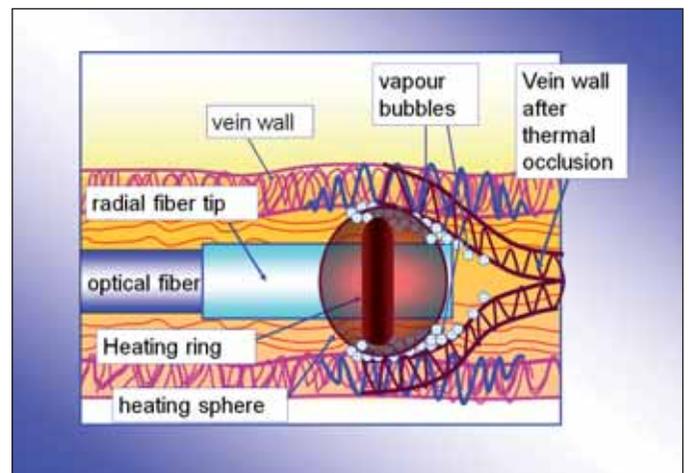
Fig. 8 - Thermal distribution of heating in ELVeS treatments with *ring radial fiber* linked with 1470nm diode laser.

J. A. Fernández

A mathematical analysis using 1470nm
and radial emitting fiber

A mathematical analysis using 1470nm and radial emitting fiber

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ABSTRACT

Background and Objectives

Endovascular Laser Treatment has proven to be a safe and efficient technique. However, its success depends on the selection of optimal parameters required to achieve optimal vein damage while avoiding side effects. Mathematical analysis may be useful to provide a better understanding of the processes involved and to determine the optimal treatment parameters as a function of vein diameter.

Mathematical Analysis

This mathematical analysis is based on new ELVeS® PainLess technique (Biolitec AG). As a consequence, we considered a 1470nm wavelength, emitted in continuous mode (CW) through a radial emitting fiber. Laser effect on vessels is determined by means of calculations describing the increase in temperature in the tunica intima (endothelium), taking into account irreversible collagen denaturation. Furthermore, heat loss to perivenous tissue is calculated in order to improve analysis accuracy. The geometry to simulate was based on a 2D model consisting of a cylindrically symmetric blood vessel including a vessel wall and surrounded by perivenous tissue. Time needed to achieve damage to the vein wall was calculated for 3 and 5 mm vein diameters, using a laser power of 5W. Finally, the total dose was expressed in joules per centimeter in order to compare theoretical analysis with clinical experiences.

Results

The time required for treating 1 cm of a 5 mm diameter vein is **4.4 s** when not considering heat loss to surrounding tissue. According to this, energy per unit of length necessary for treating a 5mm diameter vein will be **22 J/cm**, irradiating with 5W. Considering heat loss, time required for treating 1 cm of a 5 mm diameter vein is 5s, resulting in an energy per unit of length of **25 J/cm**. In the case of a 3mm diameter vein, the time required for treating 1cm is **1.5 s**, not considering heat loss. Thus, for laser power of 5W, energy per unit of length necessary will be **7.5 J/cm**. Considering heat loss, time required for treating 1 cm of a 3mm diameter vein is **1.6s**, leading to an energy per unit of length of **8 J/cm**.

Conclusions

The parameters determined by the present mathematical analysis are in agreement with those used in clinical practice with the EVLA technique. They confirm that thermal damage of the inner vein wall (tunica intima) is achieved using lower power values when comparing to other endovascular laser treatments. Due to this and the fact that calculated heat loss is low, this innovative technique may be carried out without tumescent anesthesia, obtaining excellent results regarding to vein closure and level of pain during treatment. In addition, not having to make use of tumescent anesthesia leads to faster, simpler and safer treatments, with improved outcomes. The even emission achieved using radial emitting fibers reduce vein perforation risk and its associated complications. As a consequence, symmetrical vein shrinkage is achieved, reducing localized perivenous tissue damage and recanalization probabilities.

Introduction

The venous system comprises valves, whose main function is to achieve unidirectional blood flow back to the heart. Venous valves are usually bicuspid valves, with each cusp forming a blood reservoir, which force their free surfaces together under retrograde blood pressure. As a consequence, when properly operating, retrograde blood flow is prevented, allowing only antegrade flow to the heart. A valve becomes incompetent when their cusps are unable to seal properly under retrograde pressure gradient, so retrograde blood flow occurs.

When retrograde blood flow occurs, pressure increases in the lower venous sections, dilating veins and usually leading to additional valvular failure. Lower-extremity venous insufficiency is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins.

Varicose veins are frequently treated by eliminating the insufficient veins. This forces the blood to flow through the remaining healthy veins. Various methods can be used to eliminate the problem insufficient veins, including, surgery, sclerotherapy, and electro-cautery. Usually these methods are associated with significant perioperative morbidity.

In order to reduce morbidity and improve recovery time, minimally invasive techniques have been developed as alternatives to surgery in the last few years.

Endovenous laser treatment is one of the most frequently used among these new techniques. Numerous wavelengths have been used to carry out this treatment. Recently, usage of 1470nm wavelength (biolitec AG) has proven to be more efficient and safer than previous techniques. In addition, the development of radial emitting fibers (biolitec AG) has given even more security and accuracy to endovenous laser treatment. Laser radiation induces a heating of the vein wall which is necessary to cause collagen contraction and necrosis of endothelium.

The introduction of these two new features (1470nm and radial emitting fiber) to the technique has allowed performing endoluminal laser treatments without tumescent anesthesia, obtaining excellent results regarding to vein closure and absence of pain during treatment. Successful laser treatment must achieve permanent damage of the vessel wall, but essentially the tunica intima (endothelium).[1] However, it is also believed that the tunica adventitia must be heated sufficiently to achieve efficient closure.

Conversely, to avoid side effects, damage of the perivenous tissue must be avoided.[2] The aim of this work is to present a mathematical analysis for describing ELVeS® PainLess Technique (Biolitec AG) based on a geometrical model and physical assumptions that can be applied to this model, regarding heat conduction and loss. Results are then compared to data reported in clinical experience. Parameters emerging from these calculations can be taken into account for improving endovascular laser technique.

Mathematical Analysis

Geometrical model

The geometrical model is assumed to have cylindrical symmetry, based on the advantageous features of the radial emitting fiber (biolitec AG). In fig. 1, a schematic picture of the geometrical model is depicted, showing fiber and vein radius notation.
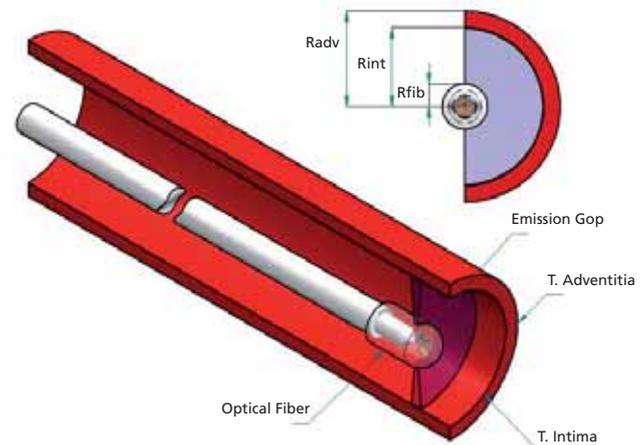
Fig. 1 - Geometrical model of venous laser treatment with radial emitting fiber.

Mathematical analysis

Usually, bibliography related to mathematical modeling of endovascular laser treatment describes models for wavelengths which are not highly absorbed in the substance placed between laser source and target, such as 810nm.[2, 3, 4]

As a consequence, these mathematical models generally consist in three main calculations:

- Laser light distribution (Diffusion approximation of the transport theory)
- Temperature rise due (Bioheat equation)
- Laser-induced damaged (Arrhenius damage model).

Calculation of laser light distribution is useful when the wavelength used is not completely absorbed in the substance (blood in this case) placed between the source and the target (tunica intima). When using a highly-absorbed wavelength (as in this analysis, 1470nm wavelength is used, which has an absorption coefficient of over 10 times greater than 980nm), electromagnetic energy is almost completely absorbed inside vessel lumen and converted into heat. Thus, electromagnetic energy itself wouldn't be directly responsible for laser effects, but heat would. Heat is then transmitted by conduction to the surrounding structures.

Worth mentioning is the fact that, despite its low absorption in hemoglobin, 1470nm wavelength is highly absorbed in blood, due to its high content of water (around 60%, for normal hematocrit). Cecchetti has confirmed this by means of in-vitro experiments, as can be seen in fig. 2.[5]
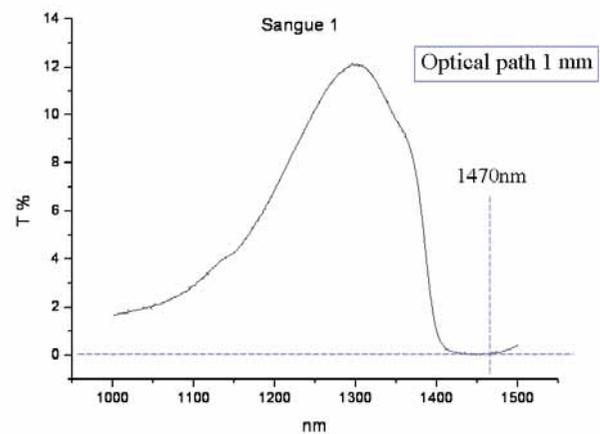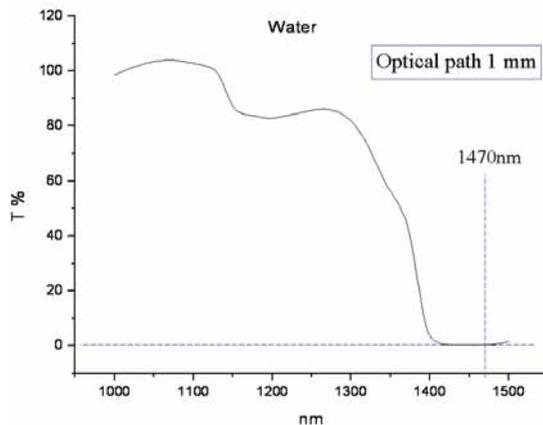
Fig. 2 - Laser radiation transmittance along a 1 mm path. Water and blood absorb almost all radiation at 1470nm.

Due to all previously mentioned assumptions, we consider the laser source, emitting at 1470nm, as a heat source, when using it for endovenous treatments. Furthermore, due to its special configuration, we will consider the radial emitting fiber as positioned in the center of the vein lumen, emitting evenly around its entire circumference. In the following analysis, calculations are initially performed not considering heat loss. Then, heat loss is estimated and considered in calculations.

Temperature increase in Tunica Intima: Calculation with no heat loss
As previously mentioned, we consider the laser source as a heat source placed in the center of the vessel. As a consequence, this heat source will cause a temperature increment inside the vein. For this mathematical analysis, we will consider a cylindrical sample volume of material placed inside the vein. Theoretical analysis will also be based on continuous (CW) radiation. Mordon et al.[2], by means of a mathematical model, have found that continuous radiation is less efficient than pulsed radiation, but still the former is easier to use and it is the method mostly used by physicians.

According to the specific heat equation, we have:

$$\Delta Q = m \, c_e \, \Delta T$$

where,
- ΔQ is the thermal energy applied [J]
- m is the mass of the sample volume [g]
- c_e its specific heat [J/(g °C)]
- ΔT is the temperature increment [°C]

As **m** y c_e are constants, if we derive with respect to time in both sides of equation (1):

$$\frac{dQ}{dt} = m \, c_e \, \frac{dT}{dt}$$

m can be expressed as the product of density **ρ** and volume **V** of the sample (cylindrical). dQ/dt is the power **P** delivered to the sample. As we consider a cylindrical geometry, **V** can be substituted by the product of the area A and the length **L**, yielding:

$$P = \rho \, A \, L \, c_e \, \frac{dT}{dt}$$

where the area **A** is:

$$A = \pi \left(R_{int}{}^2 - R_{fib}{}^2 \right)$$

Considering radial emitting fiber configuration, power per unit of length P_{LENGTH} can be derived from the knowledge of the distance between opposing cones, i.e., emission gap length:

$$P_{LENGTH} = \rho \, A \, c_e \, \frac{dT}{dt}$$

From this equation, **T** as a function of time can be calculated:

$$T = To + \left(\frac{P_{LENGTH}}{\rho \, A \, c_e} \right) t$$

where **To** represents initial temperature.

Finally, the time required for the temperature to reach a determined value will be:

$$t = \Delta T \, \frac{\rho \, A \, c_e}{P_{LENGTH}}$$

By using equation (7), we can calculate the necessary time to reach a determined temperature in the sample volume. As the fluid inside the vessel is considered the sample volume, which is in direct contact with the tunica intima (endothelium) and its flow is neglectable, the calculated temperature can be assumed to be equal to the endothelium temperature.

Heat loss to perivenous tissue
As previously mentioned, damage to the intima is determining of vessel closure. However, it is believed that the tunica adventitia must be heated sufficiently to achieve an efficient closure. This is accomplished by means of heat conduction, from the endothelium to the adventitia.
Conversely, it is necessary to avoid thermal damage to the perivenous tissue, due to the side effects related.
In order to quantify the rate of heat loss to the perivenous tissue, we assume (in accordance with numerous experiences) that the radius of action of the laser effects is limited. Outside of this radius, it can be assumed that laser has no effects.
Heat loss to the perivenous tissue can be analyzed by separating the heat path in two components (cylindrically symmetric): heat loss from the intima to the adventitia ($P_{LENGTHLOSS1}$) and heat loss from the adventitia to the perivenous tissue ($P_{LENGTHLOSS2}$). The following equations describe heat loss through concentric cylinders, which is a good approximation for this analysis.

Heat loss Intima-Adventitia

$$P_{LENGTH_{LOSS1}} = \frac{k_v \, 2\pi \, \Delta T}{\ln(R_{adv}/R_{int})}$$

where,
- $P_{LENGTHLOSS1}$ is the power loss per unit of length from the intima to the adventitia [W/mm]
- k_v is the thermal conductivity of vessel [W/(mm °K)]
- ΔT is the temperature gradient [°K]
- R_{adv} is the adventitia radius [mm]
- R_{int} is the intima radius [mm]

Heat loss Adventitia-Perivenous Tissue

$$P_{LENGTH_{LOSS2}} = \frac{k_t \, 2\pi \, \Delta T}{\ln(R_{per}/R_{adv})}$$

where,

- $P_{LENGTHLOSS2}$ is the power loss per unit of length from the adventitia to the perivenous tissue [W/mm]
- k_t is the thermal conductivity of perivenous tissue [W/(mm °K)]
- ΔT is the temperature gradient [°K]
- R_{per} is the perivenous tissue radius [mm]
- R_{adv} is the adventitia radius [mm]

Temperature increase in Tunica Intima:
Calculation considering heat loss

Previously, the time required to reach a determined temperature was calculated considering that no heat loss occurred. However, we have just estimated heat loss to perivenous tissue, that will "cool" tunica intima by means of heat conduction to surrounding structures. By using this information, the time required to reach a determined temperature considering heat loss can be calculated. As seen before, heat loss can be described by two components: heat loss from the intima to the adventitia ($P_{LENGTHLOSS1}$) and heat loss from the adventitia to the perivenous tissue ($P_{LENGTHLOSS2}$). For time calculation, both terms have to be subtracted from the PLENGTH of the laser source, yielding:

$$t_H = \Delta T \frac{\rho \, A \, c_e}{P_{LENGTH} - (P_{LENGTH_{LOSS1}} + P_{LENGTH_{LOSS2}})}$$

As can be seen from equation (10), the denominator will be lower than the denominator of equation (7), leading to a longer time needed to reach the same temperature, as was expected.

Results

For numerical calculations, we considered the necessary parameter values based on theoretical and empirical experiences. Laser wavelength used for this model is 1470nm. As explained previously, this wavelength is essentially fully absorbed in water and in blood (due to its high content of water), so for our calculations, it is appropriate to consider the sample volume as composed only by *water*. Thus, density ρ and specific heat c_e values used to calculate the time needed to increase temperature to a determined value will be:

$$\rho = \frac{1}{1000} \left[\frac{g}{mm^3}\right]$$

$$c_e = 4.186 \left[\frac{J}{g \, °C}\right]$$

According to emission features of the radial emitting fiber (biolitec AG), power per millimeter can be assumed to be equal to the laser power chosen (assuming an emission gap of *1 mm*). Fiber diameter at emission section is *1 mm*. Furthermore, clinical experiences with this fiber have show that 5W are usually sufficient to achieve an efficient vein closure.[6] As a consequence:

$$R_{fib} = 1 \, [mm]$$

$$P_{LENGTH} = 5 \left[\frac{W}{mm}\right]$$

According to bibliography[7] and experimental trials, the temperature necessary to achieve collagen irreversible damage is about *65 °C*. For this reason, we have chosen this value as the temperature to be reached in the intima. Logically, initial temperature in sample volume is *37 °C*.

The capability of laser energy to affect tissue's physical properties is assumed to be circumscribed within a concentric cylinder with a diameter of *10 mm* (in all cases). Actually, the field of action can be lesser than this, but we chose this value as a safe approximation.

Finally, calculations have been performed for two vein diameters typically found in clinical practice: 3 and 5 mm. Vessel thickness is supposed to be *0.5 mm* for both vein diameters.

Temperature increase in Tunica Intima: Numerical Calculations

Vein diameter 5mm

- *Not considering heat loss*
  For this vein diameter, radius values are the following:
  o R_{int} = 2.5 mm
  o R_{adv} = 3 mm

With these parameters, the time required to reach 65°C per millimeter of tunica intima will be:

$$t_{5mm} = \Delta T \frac{\rho \, A \, c_e}{P_{LENGTH}} = (65 - 37) \frac{1/1000 \, \pi \, (6.25 - 0.25) \, 4.186}{5} \, [s] = 0.44 \, [s]$$

As a consequence, the time required for treating 1cm of a 5mm diameter vein will be 4.4s when no considering heat loss to the surrounding tissue. According to this, energy per length necessary for treating a 5mm diameter vein will be 22J/cm, which is in concordance with clinical experience. Furthermore,

fiber withdrawal speed will have to be 2.3 mm/s, when radiating in continuous mode.

- **Heat Loss calculation**

In order to calculate heat loss to surrounding tissue, we assume that the temperature in the tunica adventitia is about **40°C**, which is considered to represent the lower temperature value from which damage to tissue begins.

From equations (8) and (9), heat loss can be calculated as:

Heat loss Intima-Adventitia

$$P_{LENGTH_{LOSS_1}} = \frac{k_v\, 2\pi\, \Delta T}{\ln(R_{adv}/R_{int})} = \frac{5.6\ 10^{-4}\ 2\pi\ (65-40)}{\ln(3/2.5)} = 0.48 \left[\frac{W}{mm}\right]$$

Heat loss Adventitia-Perivenous Tissue

$$P_{LENGTH_{LOSS_2}} = \frac{k_t\, 2\pi\, \Delta T}{\ln(R_{per}/R_{adv})} = \frac{5.6\ 10^{-4}\ 2\pi\ (40-37)}{\ln(5/3)} = 0.02 \left[\frac{W}{mm}\right]$$

- **Considering heat loss**

By using previous calculated values regarding to heat loss, we are now in condition to determinate the necessary time to reach collagen denaturation temperature considering heat loss. From equation (10), it yields:

$$t_{H5mm} = \Delta T \frac{\rho\, A\, c_e}{P_{LENGTH} - \left(P_{LENGTH_{LOSS_1}} + P_{LENGTH_{LOSS_2}}\right)}$$

$$= (65-37) \frac{1/1000\ \pi\ (6.25-0.25)\ 4.186}{5 - (0.48 + 0.02)} = \mathbf{0.5\ [s]}$$

As can be expected, t_H value is greater than t, i.e., when considering heat loss, time to reach desired temperature will be longer. Furthermore, it can be seen that heat loss from the vessel to perivenous tissue is insignificant.

In this case, the time required for treating 1cm of a 5mm diameter vein, considering heat loss, will be **5s**. As a consequence, energy per length necessary for treating a 5mm diameter vein will be **25 J/cm** which is in concordance with clinical experience. Furthermore, fiber withdrawal speed will have to be **2 mm/s**, when radiating in continuous mode.

Vein diameter 3mm

- **Not considering heat loss**

  For this vein diameter, radius values are the following:
  o Rint = 1.5 mm

o Radv = 2 mm

With these parameters, the time required to reach 65°C per millimeter of tunica intima will be:

$$t_{3mm} = \Delta T \frac{\rho\, A\, c_e}{P_{LENGTH}} = (65-37) \frac{1/1000\ \pi\ (2.25-0.25)\ 4.186}{5} [s] = \mathbf{0.15\ [s]}$$

As a consequence, the time required for treating 1cm of a 3mm diameter vein will be **1.5s**. According to this, energy per length necessary for treating a 3 mm diameter vein will be **7.5 J/cm** which is in concordance with clinical experience. Furthermore, fiber withdrawal speed will have to be **6.67 mm/s**, when radiating in continuous mode.

- **Heat Loss calculation**

In order to calculate heat loss to surrounding tissue, we assume that the temperature in the tunica adventitia is **40°C**, which is assumed to represent the lower temperature value from which damage to tissue begins.

From equations (8) and (9), heat loss can be calculated as:

Heat loss Intima-Adventitia

$$P_{LENGTH_{LOSS_1}} = \frac{k_v\, 2\pi\, \Delta T}{\ln(R_{adv}/R_{int})} = \frac{5.6\ 10^{-4}\ 2\pi\ (65-40)}{\ln(2/1.5)} = 0.3 \left[\frac{W}{mm}\right]$$

Heat loss Adventitia-Perivenous Tissue

$$P_{LENGTH_{LOSS_2}} = \frac{k_t\, 2\pi\, \Delta T}{\ln(R_{per}/R_{adv})} = \frac{5.6\ 10^{-4}\ 2\pi\ (40-37)}{\ln(5/2)} = 0.01 \left[\frac{W}{mm}\right]$$

- **Considering heat loss**

By means of previous calculated values regarding to heat loss, we are now in conditions to determinate the necessary time to reach collagen denaturation temperature considering heat loss. From equation (10), it yields:

$$t_{H5mm} = \Delta T \frac{\rho\, A\, c_e}{P_{LENGTH} - \left(P_{LENGTH_{LOSS_1}} + P_{LENGTH_{LOSS_2}}\right)}$$

$$= (65-37) \frac{1/1000\ \pi\ (2.25-0.25)\ 4.186}{5 - (0.3 + 0.01)} = \mathbf{0.16\ [s]}$$

As can be expected, t_H value is greater than t, i.e., when considering heat loss, time to reach desired temperature will be longer. However, in this case the difference is not significant, meaning that heat loss to perivenous tissue is not important. In this case, the time required for treating 1 cm of a 3 mm diameter vein, considering heat loss, will be **1.6 s**. As a consequence, energy per unit of length necessary for treating a 3 mm diameter vein will be **8 J/cm** which is in concordance with clinical experience. Furthermore, fiber withdrawal speed will have to be **6.25 mm/s**, when radiating in continuous mode.

Discussion

This mathematical analysis was developed in order to provide a theoretical backup to results obtained in clinical practice. In addition, treatment parameters can be optimized taking into account this kind of analysis. However, as it is a mathematical analysis, errors may emerge due to the assumptions and simplifications made.

Soracco et al.[6] used 1470nm diode laser (biolitec AG) in venous insufficiencies with a mean power 5W, continuous mode and a pull-back speed of 2 mm/sec (5 to 50 joules/cm) with radial emission fiber (biolitec AG). With these parameters, mean energy per unit of length delivered was 25 J/cm, which is in accordance with the parameters determined by this mathematical analysis. As we stated previously, it has been proven by Proebstle that, when performing endovascular laser treatment, permanent occlusion can be obtained by thermal damage of the tunica intima (endothelium) only.[1] This observation is confirmed by the histological study performed by Corcos et al. They showed that when permanent occlusion was observed, the endothelium and intima were always damaged and that success was independent of the vessel wall thickness.[8]

Recently, Soracco et al. proposed an additional step for this technique, by injecting saline solution inside the vein while lasing (or immediately after). As a consequence, two beneficial effects are obtained: vein spasm (thus reducing vein diameter) and increase in absorption coefficient (because 1470nm wavelength is slightly more absorbed in water than in blood). These effects would suggest an improvement in laser treatment efficiency. However, according to present analysis, special emphasis must be put on: liquid temperature and velocity. Liquid temperature is essential because if saline solution is colder than 37 °C, lasing time period will probably be longer for each vein segment, thus increasing energy per length delivered. Fluid velocity may also be an important parameter, because heat loss rate will depend on the quantity of thermal energy taken away by the liquid as it flows. These drawbacks could probably be compensated by vein diameter reduction and absorption coefficient increase, but further research should be done.

Conclusions

The parameters determined by this mathematical analysis are in agreement with those used in clinical practice. They confirm that thermal damage of the inner vein wall (tunica intima) is achieved using lower power values when comparing to other endovascular laser treatments. Due to this and the fact that calculated heat loss is low, this innovative technique may be carried out without tumescent anesthesia, obtaining excellent results regarding to vein closure and pain during treatment. Thus, if optical fiber is withdrawn at the calculated velocity and emitting at the power proposed, vein can be treated along its entire length leading to permanent occlusion.

In addition, not having to make use of tumescent anesthesia leads to faster, simpler and safer treatments, with improved outcomes. Heat loss calculations show that it doesn't affect laser parameters significantly.

Another advantageous feature of this technique is based on the even emission achieved using radial emitting fibers, which reduce vein perforation risk and its associated complications. As a consequence, even vein shrinkage is achieved, reducing localized perivenous tissue damage and recanalization probabilities.

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J. H. G. Ferreira

Endovenous Laser Ablation (EVLA):
lessons learned during the last 10 years

Endovenous Laser Ablation (EVLA): lessons learned during the last 10 years

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Introduction

In 2000, Dr Bonnet presented an alternative way to treat saphenous refluxes using endovenous laser (EVLA) at the 10th Pan-American Congress of Phlebology in Córdoba, Argentina. He used an 810nm laser unit to deliver energy to the inner part of the vein through an optical fiber inserted percutaneously. After some earlier attempts, from this date the treatment of varicose disease was changed forever with a method now proved to have many advantages for practitioners and patients. Research consultant envisaged a continuous growth of this minimally invasive alternative against surgery from an early stage and today EVLA has became the new "gold standard" in some developed countries (fig. 1). The technique is easy to learn, minimally invasive and can be done under local anesthesia with minimal discomfort in an outpatient way. Results are excellent both functional and aesthetically with high success rates, low complication index, quick recovery time, fast return to work and high satisfaction scores.

Our group has been doing EVLA treatments since 2000 and the objective of this paper is to share what we've learned during these 10 years and show the latest advances in this exciting technique. We hope this will help new colleagues to shorten their learning curve and contribute with some tips for more experienced ones.

Materials

To perform EVLA it is necessary to have a *laser system* with a suitable *delivery kit* (disposable fiber optic and introducer set) and a good *ultrasound* preferably with color Doppler.

Laser system: over the years we used two different types of laser to perform EVLA: blood absorbed lasers which work with wavelengths from 810 to 980nm, and more recently the new generation of water absorbed lasers of 1470nm (ELVeS® PainLess by biolitec AG - Germany). Water absorbed lasers have higher and more specific absorption on the vein wall allowing the use of less power and energy (fig. 2). This leads to a significant reduction in pain and discomfort for the patient (making the procedure virtually free of pain) and leaves no bruising during the postoperative period.

Delivery kit: the laser energy is delivered to the inner part of the vein through a fiber optic. They are thin and flexible allowing endovenous navigation but at the same time ultrasound visualization. Made of highly purified glass (Silica, quartz etc.)

Millennium Research Group
Market Growth (Number of U.S. Procedures and Estimated Projections. Varicose veins.

Year	Surgery All forms	PERCENT	RF	PERCENT	EVLT	PERCENT	TOTALS
1999	155,000		?		1,000	0.06%	156,000
2000	?		?		?	?	?
2001	?		?		?	?	?
2002	152,520	93%	9,840	6%	1,640	1%	164,000
2003	150,000	81%	12,000	6%	25,000	13%	187,000
2004	148,000	60%	42,000	16%	55,000	22%	245,000
2005	140,000	43%	60,000	18%	120,000	37%	320,000
2006	110,000	29%	80,000	21%	180,000	49%	370,000
2007	70,000	16%	95,000	22%	260,000	61%	425,000
2008	25,000	5%	130,000	26%	340,000*	68%	495,000
Overall	950,520	40%	428,840	18%	981,640	41%	2,362,000

Fig. 1 - Millennium Research Group.
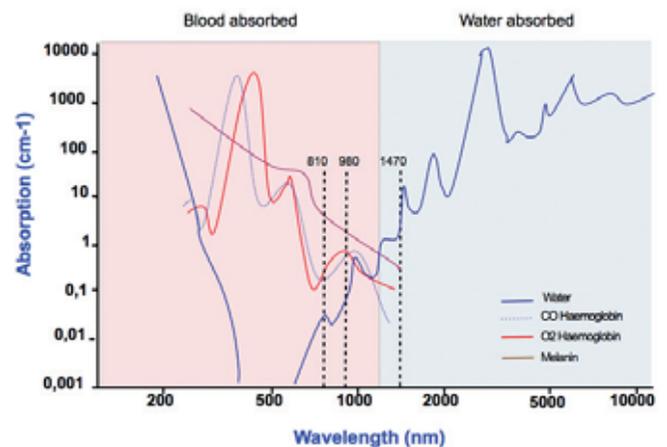
Fig. 2 - Blood and water absorption.

they act as a waveguide that transmit light from source to tissue by internal reflection. This is achieved by the cladding layer around the fiber core, which is specific for each laser type/wavelength. To add rigidity and flexibility, a plastic jacket covers them (fig. 3). Production of these devices is highly regulated and the best way to guarantee efficacy and reproducibility of each procedure is by using controlled and single use disposable kits. Low quality fibers lead to poor transmission properties and possibly to bad results or sections of vein not properly closed (fig. 4). There are different diameters (core diameter) but the one mostly used for EVLA is 600um and most of the fibers deliver energy frontally at the tip inside the vein (bare tip fibers). However, recently a revolutionary radial emission fiber was introduced which spreads laser energy around 360º targeting evenly all the layers of the venous wall (fig. 5).

Ultrasound: To obtain quality images the minimal configuration is a device with grayscale display and a linear transducer of 10MHz but the preferred standard is a color Doppler ultrasound.

Method

Standard technique: The patient is positioned on the table in anti-Trendelenburg position with the leg slightly abducted and a tourniquet placed at the thigh to fill the vein. Under duplex control, the best point to approach the GSV is selected and anesthetized using 0,5 to 2,0 ml lidocaine. Using US guidance, a percutaneous puncture of the GSV is done and a guide wire inserted. Once the guide wire is placed, the needle is removed and the introducer sheath inserted over them. The guide wire and the dilator are then removed and the optical fiber is inserted into the sheet and advanced up to the SFJ and positioned just below the epigastric vein.

Anesthesia: If a blood-absorbed laser is used, Tumescent Local Anesthesia (TLA) is recommended and it is done under US guidance. All the segment of the GSV to be treated is anesthetized using 0.3% lidocaine. TLA provides excellent anesthesia while the water buffer around the vein helps on preventing nerve damage. More recently, with the use of a water-absorbed laser (1470nm) together with a Radial emission fiber, TLA is not necessary which allows to visually follow the ablation in real-time and reduces the whole procedure time. We also perform the treatment on a routine basis using *Ultrasound Guided Femoral Nerve Block* or neurolepto anesthesia.
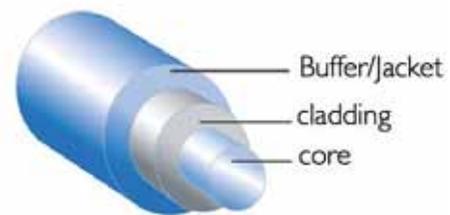
Fig. 3 - Cladding layer around the fiber core.
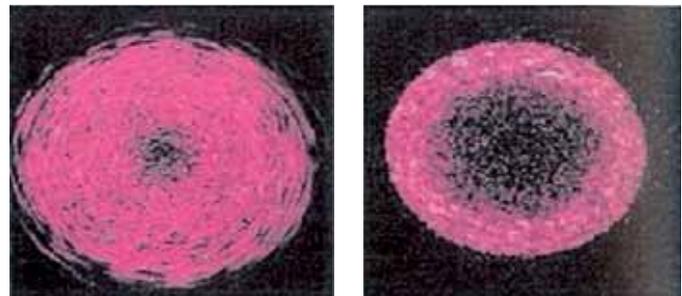
Fig. 4 - Optical fiber after use with significant reduction in conductivity.

Fig. 5 - Revolutionary radial emission fiber.

Laser ablation: After double-checking the position of the fiber tip the ablation procedure starts by firing the laser on the desired setting and withdrawing the fiber with a continuous traction. The whole procedure needs to be followed by US and is considered completed when the desired length of the vein is treated.

Tips and tricks

1. **US image optimization:** As we recommend doing the whole treatment under US guidance, image optimization is desirable to facilitate the procedure. It is good practice to remove all the bubbles between the probe and the plastic cover to achieve clear images. Depth of range needs to be adjusted using a minimum necessary for our target. Select the correct focal zones, turn down the gain and adjust the TGC sliders to obtain clear images.
2. **Accessing the vein:** As we mentioned earlier, we use a tourniquet and appropriate position of the patient to help vein access. However, in some cases (and usually during the learning period or on patients with very thin veins) this may be difficult. In these situations, is useful to use both axial and transversal view to follow the needle entering the vein. If it is still not possible to gain access, a direct approach with a mini incision should be considered and the vein retrieved using a Muller hook.
3. **Guide wire introduction:** If it is difficult to advance the guide, observe the tourniquet is removed and try to identify the problem with US to facilitate the navigation. If the problem remains, it is normally useful to rotate the leg internally or externally to straighten out the vein. Other solutions may be the use of a thinner hydrophilic wire. Finally, a second puncture could be considered.
4. **Dilator/Sheath introduction:** If dilator/sheath is hard to introduce first try by doing a small cut in skin using a scalpel. The *corkscrew maneuver* is also useful, and consists in rotating the dilator/sheath over its axis.
5. **Laser aiming beam:** If room lights are dimmed, this is very useful to follow the fiber insertion.
   When fiber tip is in position at the SFJ, aiming beam should be clearly visible. If not check that the fiber is not entering the deep venous system.
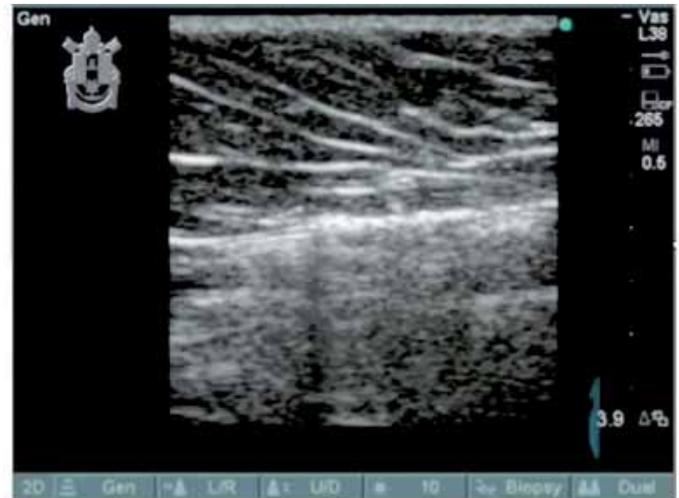
Fig. 6 - White line

Fig. 7 - Pearl sign

6. **Fiber tip:** If the tip of the fiber is not clearly visible, the US image needs to be optimized. You could also follow the fiber from the entering point using a transversal view.
7. **IMPORTANT:** Never fire the laser before exhaustively checking the fiber position.

Laser parameters

The variety of laser wavelengths (810, 940, 980, 1064, 1470, etc.) and the large number of centers around the world performing this treatment have created confusion around this procedure, and several protocols were proposed for obtaining an optimal result. Setting measurable parameters such as energy per centimeter of vein treated (J/cm), fluence (J/cm^2), irradiance (fluence/s), Power (watts), and delivery mode (continuous pullback or pulsed mode) helps on unifying the criteria.
In April 2005 a group of doctors with significant experience on the treatment, met in Abano Terme (Italy) to call for the standardization of this treatment and founded the International Endovenous Laser Working Group (IEWG).
According with the consensus of the IEWG in those days, when blood absorbed lasers were mostly used, best results are obtained using around 100 joules per centimeter in continuous mode with power values of ranging from 10 to 15 watts.
With the use of water-absorbed lasers (1470nm) in combination to a Radial fiber, we set power between 5 to 7 watts.
As energy is delivered and fiber withdrawn, the vein wall shrinks but this response is not even along the tract and also some veins contract more than others.
Venous diameter is one of the factors, but we observed that veins with the same diameter also contract unevenly probably by differences in venous wall structure. There are mathematical models for this laser systems and in-vitro experiments that suggest LEED values around 35 to 40 joules per centimeter. However, due large variations in venous shrinkage we recommend that the closure process should be controlled in real time with US to guarantee complete vein closure. We still believe that the eye of the surgeon should be critical for the success of the operation, being a scalpel or laser the tool of choice, and that is difficult to replace with a mathematical formula.

Ultrasound aiding to control the closure process in real time

As mentioned previously, the treatment was initially performed using TLA to obtain anesthesia, good contact between the fiber and the vein wall (important for some wavelengths) and to create a buffer for preventing damage of surrounding tissue. The problem is that the quality of the ultrasound image is reduced because of the large amount of liquid injected around the vein. So, the doctor cannot be sure that the treated vein is really closed. In fact, some doctors even skipped the use of US during the ablation part of the treatment for this reason. As a result, is that in some patients the vein doesn't close completely (luckily on a small percentage) and the blame of course is laid on the doctors and the technique.
Using the newer laser of 1470nm with radial fibers, and performing the treatments with No-TLA, we recognize five ultrasound markers of venous closure:

- **The White Line:** the white line is seen using the longitudinal ultrasound view and is the result of the contraction of the proteins, collagen and elastic fibers of the vein wall (fig. 6).
- **The Pearl Sign:** in the transversal view it is possible to see the pearl sign. In the same way as the white line, the cross section of the saphenous vein goes white and is shaped like a pearl (fig. 7).
- **Inversion of bubble direction:** this results as the vein is closed proximally, and bubbles have only one-way out: Backwards.
- **Vein Incompressibility:** is the result of vein wall tightening and contraction of its proteins, collagen, elastic fibers, etc. To detect this marker it is necessary to press the vein firmly with the US transducer in a cross section view.
- **Absence of blood flow:** is the definitive proof that the vein is closed. To check this marker it is necessary to have a color ultrasound. It is possible to check both in longitudinal or cross section view.

Conclusions

The objective of this paper was to share what we've learned during these 10 years and show the latest advances in this exciting technique. It is important to keep in mind that although this technique could look easier than surgery, it involves the use of different technologies (laser and US imaging) and

minimally invasive methods, which require adequate training for a successful operation. We proved over the years that best results with minimal complications are achieved using lower energy settings by following the ultrasound control criteria. The use of modern laser sources and radial emission fibers allows performing this procedure without TLA with excellent results reducing time and discomfort for the patient.

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J. E. Soracco

New Generation 1470nm Laser Optical Fibers

New Generation 1470nm Laser Optical Fibers

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In the evolving area of endovenous laser treatments, new optical fibers have been developed which optimize the outcome of therapeutic vein ablation and minimize undesired collateral effects especially when used with laser devices operating at longer wavelengths, e. g. 1470nm. The objective of this paper is to present the preliminary experience developed in two centers of Argentina, combining a high power diode laser of 1470nm with different optical fibers: 1.-frontal emission and 2.-radial emission pattern. Since June 2008 to June 2009, 80 patients with superficial lower limb venous insufficiencies stratified by CEAP classification as C2-C4 were treated: 69 great saphenous veins (GSV) among which 58 were treated surgically and 11 without crossectomy, and 11 small saphenous veins (SSV) all without surgery, with prophylactic anticoagulation. The laser device operated at 1470nm in continuous mode, delivering laser radiation between 1 to 5 Watts. Pull-back speed was 2 mm/s and total linear endovenous energy density (LEED) achieved in each treatment was about 5 to 25 J/cm². 51 frontal emission fibers and 29 radial emission fibers were used. All procedures were done under ultrasound guidance verifying position of the fiber tip and therapeutic effect. All were outpatient procedures, using elastic restraint with compression stockings for 15 days after treatment. There was absence of allergic reactions, no need of tumescence (it is suggested to only separate the veins from the skin if necessary) and, as anesthetic method only sedation was necessary. All veins treated with a 1470nm laser wavelength and optical fibers with frontal and radial emission pattern were closed up to date. The combination of laser devices operating at 1470nm with radial and frontal emission optical fibers have shown the same therapeutic effect with less LEED, scarce or null side effects and minimal utilization of anesthetics than shorter laser wavelengths (805, 810, 980nm) with frontal emission fibers.

Introduction

Since the beginning of endovenous laser treatments of superficial venous insufficiency of lower limbs, in the 90s, all publications refer that energy is transmitted to the interior of the veins, impacting on the chromophore, through semi-rigid quartz optical fibers, 220, 400 or 600µm flat at their free end with frontal emission pattern, using different wavelengths of 808, 810, 940, 980, 1064, 1320nm and in the last years 1470 and 1500mn.
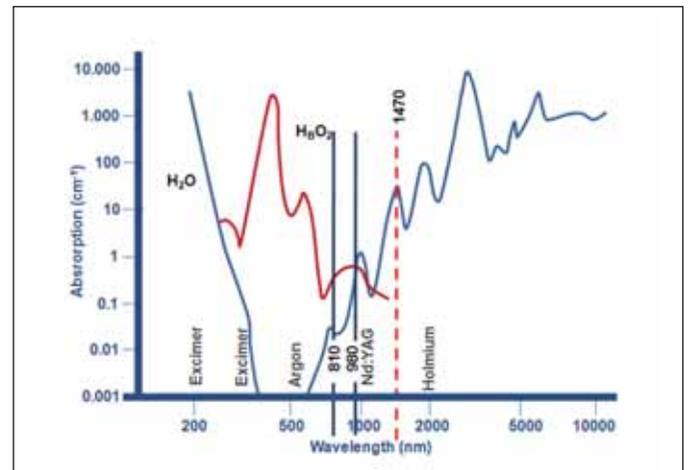
Fig. 1 - Absorption curves of hemoglobin and water.
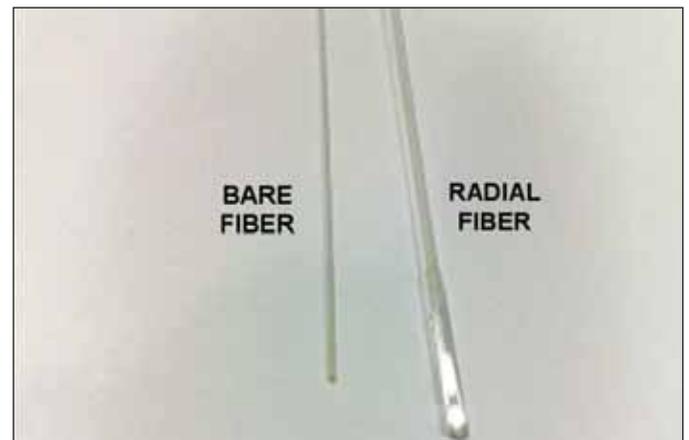
Fig. 2 - Tips of the frontal and radial emission optical fibers.

The types of diode lasers are mostly high-power gallium arsenide and the dominant chromophores are the oxy and carboxyhemoglobin up to 940nm, then water also begins to be absorbed being the exclusive target from 1320nm onwards (fig. 1). In late 2007, we began to perform endovenous ablation with a 1470nm laser, frontal emission fibers and a new type of radial tip design (fig. 2). The latter emits circumferentially, delivering laser energy evenly on the wall of the diseased vein and selectively hitting the water in the vein wall and blood. The fiber body has a mark every cm to facilitate the pull-back at a constant speed (fig. 3).

Materials and methods

We took 12 months of our initial experience. 80 patients with superficial lower limb venous insufficiencies were treated, stratified as C2-C4 according to CEAP classification. 69 GSV among which 58 were treated surgically and 11 without crossectomy (in saphenous-femoral or saphenous-popliteal junctions we made less than 10mm arch surgery), and 11 SSV all without surgery, in these cases using prophylactic anticoagulation. 51 frontal emission fibers and 29 radial emission fibers were used. The 1470nm laser device was operated in continuous mode, delivering laser radiation between 1 to 5 Watts. Venous access was performed by distal echoguided puncture, with a 6 Fr introducer set for the radial fiber and a 18G puncture needle for the bare fibers of 400µm. Pull-back speed was 2 mm/s and total LEED achieved in each treatment was about 5 to 25 J/cm^2. All procedures were done under ultrasound guidance verifying position of the fiber tip and therapeutic effect. The light absorbed by the chromophore (water) produced the desired photo-thermal effect with less LEED and attaining venous photothermocoagulation and protein retraction of the vein wall. With the frontal emission optical fibers the energy delivered through its tip produced photo-thermal exchange with blood's water and vein wall, achieving distally the initial retraction of the vein. Due to the original design of the radial emission optical fiber, the laser energy delivered to the treated vein produced a symmetric, uniform and homogenous effect in the whole vein wall, irradiating at the same time a length of 2 cm with the same pull back-speed as with the frontal emission fiber.

Fig. 3 - Amplified image of the tip of the radial emission fiber, with its body mark every cm.

Fig. 4 - Preoperative control, thigh GSV flow with reflux.

We did not conduct tumescence with this wavelength because the perivenous thermal diffusion does not affect the surrounding tissues. We only use it when we need to separate the vein from the skin. As anesthesia, conscious sedation was used being an outpatient procedure, with the use of elastic stockings of 15 to 20 mm Hg, for 15 days.

Results
Echo doppler control was performed postoperatively at 7 and 30 days and then remote controls, observing obliteration of the treated segments and resolution of the symptoms in all cases. The immediate side effects were minimum local discomfort and pain and bruising or hematoma at the access site. Scarce or null fibrosis with absence of hyperpigmentation and remote neuritis was also perceived (fig. 4 and 5).

Conclusions
The use of higher wavelengths where the primary chromophore is water, of which there is a high content in the vessels' wall and blood, associated to a new generation of optical fibers, allows for achieving the goal of the treatment, that is the ablation of the veins with less final LEED, low incidence of side effects, less anesthesia time and closure of the vein in all the cases treated.

Fig. 5 - Postoperative control, 48 hours after procedure, absence of thigh GSV flow.

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A. H. Davies

Endovenous Laser Ablation:
Experiences from the United Kingdom 2008/2009

Endovenous Laser Ablation:
Experiences from the United Kingdom 2008/2009

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ABSTRACT

Endovenous laser ablation (EVLA) is a safe and effective method of treating superficial venous reflux and has been available in the United Kingdom (UK) since 2001. At Charing Cross Hospital we have investigated post procedural discomfort and recovery times in patients following treatment with EVLA, the patients' perspective regarding EVLA and reviewed results from a survey of consultant surgeons in the United Kingdom and reports from the UK venous registry.

Patients treated with EVLA, 980nm bare fibre reported average pain scores over 3 and 10 days were 25.8/100 and 23.3/100 for 980nm bare fibre and patients took median(range) of 11(0-58) analgesia tablets over the 10 days and were able to return to work at a median(range) of 5 (0-11) days.

Although traditional surgery still remains the most frequently performed treatment for varicose veins in the UK, EVLA is increasing in popularity and was offered by as many as 35% of surgeons as first line therapy in 2009 according to the UK venous registry. EVLA is also gaining popularity amongst patients, with over 30% of those with symptomatic varicose veins aware if its use, making it the most frequently requested treatment modality.

Endovenous laser ablation (EVLA) was first described by Bonne in 1999[1] and has been available in the United Kingdom since 2001. It has been shown to be a safe and effective method of treating superficial venous reflux with excellent success rates in comparison to other treatment modalities[2]. It is becoming increasingly popular throughout the world[3-6] and offered as first line treatment in a number of centres. A number of randomised clinical trials have evaluated its use in comparison to traditional surgery, and, although results have been variable, it has been shown to be less painful[7] and result in quicker recovery times[8] in comparison to traditional surgery.

Since the original introduction of the 810nm laser[9], a number of different wavelengths of laser have been introduced from the 810nm laser designed to target haemoglobin to longer wavelengths, including 1320nm, and more recently 1470nm laser, designed to result in less post procedural discomfort as the wavelength targets water in the vein wall.[10] In addition to the introduction of new wavelengths, different designs of laser fibre have been introduced, including the 1470nm radial laser fibre and the 980nm gold coated laser fibre, both designed to lead to a more uniform heating effect, reducing the number of vein wall perforations associated with post procedural bruising and discomfort. At Charing Cross Hospital we have investigated post procedural discomfort and recovery times in patients following treatment with the 980nm bare fibre endovenous laser ablation. Results of a comparison with VNUS® ClosureFAST™ Radiofrequency ablation have recently been published in Vascular and Endovascular Surgery[5].

Over a 2 year period, patients who were referred by their general practitioner with symptomatic varicose veins underwent colour duplex scanning by an accredited vascular scientist. Patients with superficial truncal reflux >0.5 seconds with veins >3 mm were offered EVLA with 980nm laser. All procedures were performed under general anaesthesia with tumescent anaesthesia along the course of the truncal vein. Concomitant phlebectomies were also performed at the same sitting. Patients were asked to record any discomfort on a 100mm visual analogue score diary card and also to record analgesia taken and time to resume work and normal activities. A total of 36 patients were treated with EVLA, 980nm bare fibre. Average pain scores over 3 and 10 days were 25.8/100 and 23.3/100 for 980nm bare fibre respectively and patients took median (range) of 11 (0-58) analgesia tablets over the 10 days[5]. Patients were able to return to normal activities at median (range) 5 (0->11) days. The results of this study support the use of EVLA as safe and effective method of treating superficial venous reflux in patients with primary and recurrent varicose veins. The majority of patients reported mild to moderate pain following EVLA, and were able to return to work at an average of 5 days. These results are in keeping with other randomised trials comparing EVLA to traditional surgery, with the 810 nm laser where patients reported median (range) pain scores of 5-41/100(0-50) over the first 3 days[8], and the 980nm laser with average scores of 20-38/100[11] or mean (SD) of 1.9 (1.6)/10[12] over the first 48 hours. Times to resume normal activities were also similar, with the majority of patients returning to work within 1 week[8]. Data from our cohort of patients has also shown that EVLA results in significant improvements in disease specific quality of life[13], which in other trials has been shown to be equal to those achieved following traditional surgery[8-11].

Despite the interest in endovenous ablation therapies, traditional surgery remained the most frequently offered treatment in the United Kingdom as recently as 2008, which was confirmed by surveys sent to consultant vascular surgeons. Data confirmed that as many as 74% of surgeons offered surgery as first line treatment, however laser was offered as a first line treatment by 20%[6-14]. Despite predictions that over the next 5 years, traditional surgery would remain the gold standard treatment for varicose veins[6], data for the United Kingdom Venous Registry 2009 supports the notion that the popularity of EVLA is rapidly expanding, with approximately 35% of users offering EVLA, and only 50% offering surgery as their routine treatment modality[3]. As regards the choice of EVLA, the 980nm laser remains the most frequently used, in over 50% of cases, however the 1470nm laser is rapidly becoming popular and used in 27% of cases in 2009. Other frequently used wavelengths were 810, 820, 1450 and 1480nm[3].

Patients are also becoming increasingly well informed about endovenous laser ablation. In a recent questionnaire survey, over 30% of surveyed patients presenting for treatment with varicose veins were aware of laser ablation, of which 11% specifically requested EVLA (the majority of remaining patients, 72% did not express a preference), making it the most requested treatment modality[15]. Interestingly, the most concerning factor overall to patients was recurrence, followed by discomfort after treatment[15], making EVLA a highly suitable choice of treatment modality for many patients. With 80% of patients stating that their choice of treatment modality would definitely

be influenced by the opinion of their vascular surgeon, the need for high quality evidence supporting the use of new endovenous lasers is clear. Data from our research at Charing Cross Hospital provides further support for the popularity and efficacy of EVLA, and, despite the increasing popularity of radiofrequency ablation and foam sclerotherapy as well as the introduction of further novel treatments such as steam ablation, laser appears to remain the most popular of the endovenous ablation therapies both amongst surgeons and patients alike. Perhaps due to the large body of evidence to support not only its safely but excellent longer term outcomes[2], the rapidly improving technology and competitive pricing it is likely to supersede traditional surgery in the near future.

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D. Greenstein

Endovenous Laser Ablation (EVLA) using Radial and Bare-tip fibers: A Comparative Study of Energy Requirements

Endovenous Laser Ablation (EVLA) using Radial and Bare-tip fibers: A Comparative Study of Energy Requirements

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ABSTRACT

Purpose of study

Due to advances in laser fiber technology, the treatment methods for superficial venous insufficiency (SVI) using EVLA is changing. There has been a trend towards lower energy requirements. Direct comparison between different fiber type modalities is rare. The objective of this study was to evaluate and compare the energy requirements to successfully treat lower limb main-stem reflux when performing EVLA using Radial and Bare-tip fibers (Biolitec ELVeS).

Methods

A retrospective analysis of a consecutive series in 95 cases was performed. In each case there was symptomatic, primary mainstem reflux in Great Saphenous Vein (GSV) or Short Saphenous Vein (SSV). All cases had confirmed venous incompetence using colour flow duplex scans. The same operating surgeon and scrub nurse were involved in all procedures. The fiber type was chosen based on anatomical-technical considerations, tortuosity and collateral vein reflux. All patients underwent EVLA (1470nm Biolitec) using a Bare-tip fiber (n=64) or Radial-fiber (n=31). All were treated under local anaesthetic with no sedation, in the office environment. Energy was delivered in a pulsed manner in the Radial-fiber (4-7 Watts) and Bare-tip fiber (10-14 Watts) a. The total pulsed energy delivered in Joules (J) and the energy delivered per cm of vein (J/cm) was recorded per procedure. All patients had follow up duplex sonography at 1 week, 3 months and 6 months to confirm vein closure.

Results

All cases underwent successful closure of their mainstem reflux based on duplex surveillance at 1 week, 3 months and 6 months using Radial-fiber (100%, n=31). Using Bare-tip there was one failure at 3 months (98.4%, n=64). The amount of energy used in EVLA to treat the GSV using Radial-fibers was 37.9 J/cm (+/- 6.2) and the Bare-tip fiber 50.8 joules (+/- 3.9). Significance of $p < 0.001$ (Mann-Whitney U-Test). The amount of energy used in EVLA to treat the SSV using Radial-fibers was 36.1 J/cm (+/- 1) and the Bare-tip fiber 46.0 joules (+/- 5.5). Significance of $p < 0.05$ (Mann-Whitney U-Test).

Conclusions

EVLA using a Radial-fiber and Bare-tip fiber can be used to successfully close primary mainstem veins at low energies. Despite this, the energy requirements used in the Radial Fiber is significantly less than the Bare-tip. Consideration of these energy requirements may therefore be of importance in future prospective studies of EVLA.

T. King

Treatment of the small saphenous vein using 1470nm diode laser and the radial fibre

Treatment of the small saphenous vein using 1470nm diode laser and the radial fibre

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ABSTRACT

Objective

To report on our experience in using 1470nm diode laser and radial fiber (biolitec®) in treating saphenopopliteal junction incompetence and small saphenous vein reflux.

Methods

Eighty-five small saphenous veins in seventy-three patients with symptomatic small saphenous vein reflux were treated over a sixteen month period. Patients were evaluated clinically and Duplex ultrasound evaluation was performed at 3-7 days, four weeks, three months, six months, and twelve months after endovenous laser treatment.

Results

Successful occlusion of the small saphenous vein, as shown by lack of flow on Duplex ultrasound and pulsed color Doppler imaging, was demonstrated in all but five (5.9%) treated veins at one month. With observation, these junctions were seen to be closed at three months. There was one small saphenous vein (1.1%) with flow at three months that had previously been seen to not have flow. This was successfully treated with ultrasound-guided foam sclerotherapy. To date, successful occlusion has been seen in all patients who have completed their six and twelve month follow-ups. Patients experienced minimal bruising at the laser fiber access site and reported negligible discomfort along the treated vein at one week. No patient had swelling or tenderness. No nerve injury or skin burns occurred. There was no evidence of deep venous thrombosis.

Conclusions

Short and intermediate term results of endovenous laser ablation of the small saphenous vein with the 1470nm diode laser and Radial fibre appears to be highly safe and effective in the elimination of small saphenous vein reflux.

Since it received United Stated Food and Drug Administration (FDA) approval in 2002, endovenous laser ablation (EVLA) has been increasingly commonly used to treat superficial venous insufficiency due to saphenofemoral (SFJ) and saphenopopliteal (SPJ) junction incompetence, causing great saphenous (GSV) and small saphenous vein (SSV) reflux. Initially approved only for treatment of the refluxing GSV that was non-tortuous, non-aneurismal, and less than 12 mm in diameter, EVLA is now used for the treatment of virtually any refluxing vein which can be negotiated by the laser fiber and the skill of the practitioner. Along with the increasing use of endovenous laser has come an ever enlarging body of literature about the efficacy and safety of EVLA. It should be noted, however, that the vast predominance of these articles report only on treatment of the GSV.[2-4] Along with the increasingly widespread use of the endovenous laser has come the development of new lasers with different wavelengths, as well as new laser fibres. The 810nm diode laser, that was first approved by the FDA, has been joined by many others, including the 940nm, 980nm, and 1470nm diode lasers, as well as the 1319nm and the 1320nm Nd:YAG lasers. Additionally, the original single use 600 micron bare tipped laser fiber with a thick layer of protective cladding and been joined by various 200-400 micron fibres, single and multiple use fibres, bare tipped and jacketed fibres, and fibres that don't require the use of a long sheath for complete access to the vein. Included in this last type is the Biolitec Radial fibre. There are now studies that have been published involving the use of all these lasers and fibres but, to date, most of the published literature is based on the use of the older 810, 940, 980, and 1320 lasers.[2-4] Given the fact that reflux in the great saphenous vein is more common than in the SSV and that treatment of the SSV with EVLA was initially not allowed by the FDA, it is not surprising that there are only a few articles that have been written specifically about the use of EVLA for SSV reflux.[5-8] Nevertheless, GSV and SSV disease co-exist 30% of the time.[9] Moreover, even though large visible varicosities arise from the GSV 82% of the time, 18% arise from the SSV.[10] Furthermore, the SSV has been shown to contribute to 75-88% of vein disease recurrence after surgical stripping of the GSV[11], while stripping of the SSV is associated with a high recurrence and complication rate.[12] Thus, the use of EVLA in the treatment of SSV reflux, as an alternative to surgery, has become an increasingly appealing treatment possibility.

This is a report on our experience in using the Biolitec 1470nm diode laser and Radial fiber in treating symptomatic saphenopopliteal junction incompetence and small saphenous vein reflux. In this prospective series, 85 small saphenous veins in 73 patients were treated over a sixteen month period. All of the patients underwent a detailed clinical and duplex evaluation to establish the presence of symptomatic refluxing vein disease and any resultant chronic venous disorders. All patients were CEAP[13] clinical class 2 or above and had no contraindications to EVLA being performed (known untreated coagulation disorder, pregnancy, lactation, current venous thrombosis, systemic infection, poor overall general health).

As part of the patient's initial evaluation, venous duplex examination was performed in the standing position with pulsed color Doppler and Duplex venous ultrasound imaging using a 5-13 MHz ultrasound probe. More than 0.5 sec. of reverse blood flow, documented in response to manual calf compression and relaxation, was considered to be abnormal. The hemodynamic patterns within the venous system were assessed and documented in a detailed venous map. The Venous Dysfunction Score (VDS)[14] of each patient, including the venous Anatomy involved, the patient's Clinical symptoms and their severity, and their degree of Disability, was also assessed prior to treatment. Additionally, in evaluating the efficacy of any venous treatment, it is important to assess the way patients perceive their health and the impact that any treatment, or adjustment in lifestyle, might have on their quality of life. Using a patient related outcomes measure (PROM) that estimates the patient's vein disease-specific Health Related Quality of Life (HRQL) accomplished this goal. The PROM we used was the Aberdeen Varicose Vein Questionnaire (AVVQ).[15,16]

Before treatment was begun, the patient's leg was re-assessed with Duplex ultrasound and all identified segments of refluxing saphenous trunks, saphenous tributaries, and non-saphenous veins were found and marked on the skin. The patient's leg was then prepped and draped to insure sterility during the procedure. Using ultrasound guidance, a 7 cm 6F sheath was used for access to the vein and the tip of the Radial fiber was placed at the point where the SSV was seen to dive through the muscular fascia on its way to its popliteal vein confluence. After sonographic confirmation of fiber placement, tumescent anesthesia was injected. Using ultrasound guidance, a 0.1% lidocaine with bicarbonate solution was injected perivenously. Generally, patients received approximately 10 cc of tumescent solution

per centimeter of vein being treated. Once adequate tumescence was given, the laser was engaged. Energy delivery was at 6W, continuously, with a pullback speed of 1-2 mm/second, depending on the size of the vein. The point of entry of the laser fiber was no lower than the point at which the sural nerve was seen to come into contact with the SSV by sonographic examination. After treatment was finished, the patient was fitted with a thigh-high 30-40 mm Hg gradient compression stocking. Patients were instructed to wear their stocking continuously for the first 36 hours and then while awake for one week. Patients were told to take Ibuprofen 400 mg orally, four times a day if needed. No post operative narcotics were prescribed. Patients were not given anti-coagulants, unless they were already taking them chronically for other reasons. In this case, they took their usual medication without alteration in dosing or schedule. Patients were instructed to walk for at least 10 minutes before they returned home and they were told to continue to walk at least 20 minutes twice a day thereafter. Patients were instructed to go back to work the next day and, with very rare exception, were able to do so.

A total of 73 patients (50.4±12.2y) were treated. The majority of the treated subjects were females (M: F 14:59). The CEAP distribution was: 2-18%, 3-13%, 4-62%, 5-4%, and 6-3%. The average length of the treated SSV was 14.8±5.2 cm. The mean SSV diameter was 4.7±2.2 mm and the mean SPJ diameter was 4.9±2.4 mm. Out of the 85 incompetent SPJs included in the study, 5 (5.9%) continued to have any evidence of reflux at one month. With observation, these junctions were seen to be closed at three months. There was one SSV with flow at three months that was not previously seen to have flow. This was treated with ultrasound-guided foam sclerotherapy. To date, successful occlusion has been seen in all patients who have completed their six and twelve month evaluations. There were two CEAP C6 patients. Both of their ulcers closed within three months. Patients experienced minimal bruising at the laser fiber access site and reported negligible discomfort along the treated vein at one week. No one had swelling or tenderness. No nerve injury or skin burns occurred. There was no evidence of DVT. The VDS Clinical Score of all patients before treatment had a mean value of 3.3±1.3. With treatment this was significantly reduced at one month. This result was sustained at 1 year: 1.2±0.4 (p< 0.001). The AVVQ revealed marked improvement in HRQL post therapy. The initial pre-treatment mean value was 11.8±5.5.

At one month it was 8.8±5.2 (p<0.001). This remained significantly lower with time and improved to 4.5±3.6 (p<0.001) at twelve months. The results of this study clearly establish the short to intermediate term efficacy of EVLA using the 1470 nm Biolitec diode laser with the Radial fibre in the treatment of chronic venous insufficiency due to SPJ incompetence and SSV reflux. Treatment significantly improved the Health Related Quality of Life of these chronic vein disease patients.

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G. Magi

EVLA of saphenous and perforators reflux in 457 patients with venous leg ulcers - 6 year follow-up

EVLA of saphenous and perforators reflux in 457 patients with venous leg ulcers - 6 year follow-up

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ABSTRACT

Aim

Chronic venous insufficiency (CVI) with leg ulcers remains a common and challenging problem and, although conventional treatments have had varying rates of success, long-term improvement of the condition has never been consistently achieved. Many studies emphasize that the majority of patients with venous leg ulcers would benefit from surgery. Therefore, there is an ongoing need for new surgical techniques to overcome the barriers to effective treatment of this problem. Here, we report on recent experiences of treating large numbers of patients with ulcers at two centers of the IEWG (Italian endovenous working group), and present the results of a retrospective analysis of randomized patients treated with endovenous laser (EVLA) versus the same number of randomized patients treated with the conventional methods of stripping and/or foam sclerotherapy. Our analysis examines various aspects of the techniques, recovery and recurrence rates.

Methods

560 consecutive patients with an active and "difficult" venous leg ulcer (CEAP C6), who had previously received medical treatment (with the ulcers showing no sign of improvement after 4 weeks), qualified for the study. 280 were randomized for EVLA of the great saphenous vein and/or perforator veins (group A); while 280 were randomized for stripping and/or perforator interruption (group B; 20 of these received foam sclerotherapy). The patients received follow-up care until December 2009, and were evaluated by clinical and color-duplex assessment.

Results

The prevalence of perforating vein reflux was high (42%) and comparable in both groups A and B. Tests were conducted that were considered valid for 457 patients (226 of the 280 patients in Group A and 231 of the 280 patients in Group B). Overall, healing times were shorter for Group A. Healing times were significantly shorter for patients in Group A with isolated perforators reflux and combined saphenous/perforators reflux compared with similarly affected patients in Group B. On the other hand, no significant differences were found in the healing times for patients with isolated saphenous reflux in both groups. The percentage of total recurrence was lower in Group A. Almost all recurrences in both groups concerned patients who had combined saphenous and perforators reflux when testing began.

Conclusions

Based on our data and our positive personal experiences of using EVLA, particularly in the subgroups with perforating vein reflux, the correction of this reflux with minimally invasive laser surgery can be expected to heal most leg ulcers with primary CVI and reduce the recurrence of ulcers within the first three years after treatment. Another interesting data is the course of recurrence on time: while in fact group B has a constant increase of its percentage increment, in group A from year -4, this increment is much slower finally reaching a stabilization around years 5 and 6. However, the value of such treatment for saphenous reflux alone remains unclear.

Introduction

Chronic venous insufficiency (CVI) with leg ulcers (CEAP C 6) remains a common and challenging problem in Italy and worldwide. In Italy alone, it is estimated that 10% - 25% of adult males and 50% - 55% of the adult female population suffer the morbid effects of CVI[1]. Although conventional compression treatments have had varying rates of success, which are improved by effective pharmacological therapy[2], a long-term improvement in eliminating this disease has never been consistently achieved. Current methods of surgical treatment, including vein stripping, various forms of perforator interruption, CHIVA and valvuloplasty, have inconsistent outcomes. The ESCHAR study on the effects of surgery and compression on healing and recurrence demonstrated that there is no significant differences in healing times and healing rates between stripping with compression and compression alone[3]. However, the 12-month recurrence rate in this study was considerably lower for patients treated with surgery. An Italian study by Zamboni et al using CHIVA hemodynamic surgery found similar results[4]. Other studies emphasize that the majority of patients with chronic venous leg ulcers would benefit from surgery[5-7]. Many doubts persist about perforator interruption[8], particularly with SEPS which is "maddeningly difficult to prove"[9].

Valvuloplasty is very useful in selected cases only[10, 11]. There is an ongoing need for new surgical techniques to overcome the barriers to effective treatment of this problem.

A recently developed endovenous laser treatment (EVLA) opens up new possibilities for the treatment of leg ulcers. In our previous collaborative, multi-center, clinical study of 1,076 patients treated with EVLA, 73 patients were in C2-C6 (6.9%) and 11 patients in C6 (1.04%) presented reflux with venous ulcers without significant varicosities. These patients with recurrent ulceration remained ulcer-free for three years in the follow-up period[12]. Here, we report on recent experiences of treating large numbers of patients with ulcers at two centers of the IEWG (Italian endovenous working group) and present the results of a retrospective analysis of randomized patients treated with endovenous laser (EVLA) versus the same number of randomized patients treated with the conventional methods of stripping and/or foam sclerotherapy. Our analysis examines various aspects of the techniques, recovery and recurrence rates.
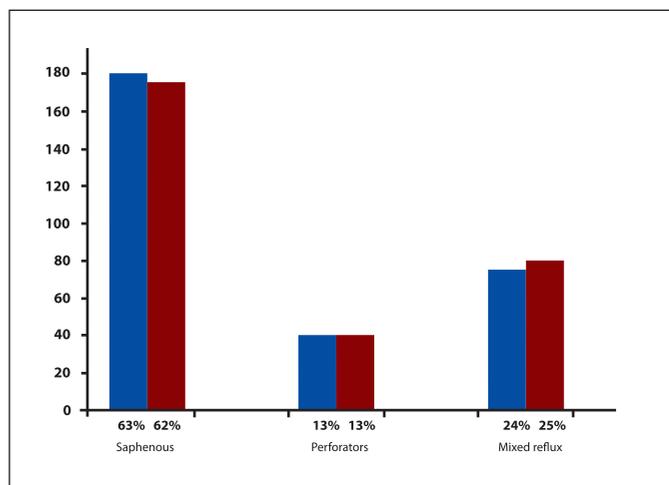
Fig. 1 - Reflux types.
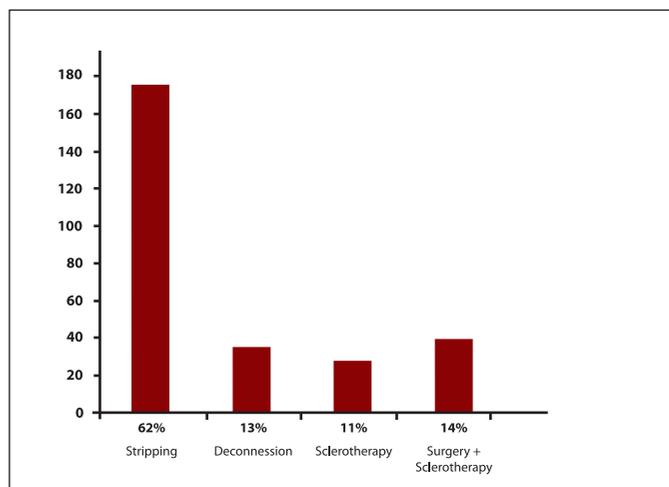
Fig. 2 - Group B patients treatment.

Materials and methods

Patients enrolled in the study were chosen from among those treated between 2002 and 2006 in the Angiology and Vascular Surgery Center at S. Giuseppe Hospital, Arezzo, and the Section of Vascular Surgery and Angiology in the Department of Specialist Surgical Sciences at the University of Milan, both accredited centers that have agreements in place with the NHS. Between January 2002 and December 2006, a group (A) of 280 patients with venous ulcers in the lower limbs was randomized for EVLA for the correction of saphenous and perforators reflux caused by venous hypertension on the basis of lesions or a delay in their repair. After their informed consent was obtained in accordance with Italian laws and regulations, all patients underwent a clinical and instrumental color-duplex (CD) examination and were awarded a CEAP rating.

The CD test was conducted in both orthostatism and clinostatism in order to perform hemodynamic venous mapping (MEV)[13]. A second group (B) of 280 patients with the same condition was simultaneously assessed using the same clinical and instrumental criteria and was treated using conventional methods to correct saphenous and perforators reflux (260 patients with saphenofemoral junction ligation and stripping and/or perforator interruption; 20 patients with foam sclerotherapy only). Both groups were randomized on the basis of the homogeneity of the clinical history of the CEAP class at the time of the first examination.

We also established that the following conditions existed in all cases:
- Absence of metabolic conditions, specifically diabetes
- Absence of concomitant peripheral arterial disease
- Persistence of ulcers for more than four months, regardless of size, and not showing any sign of improvement after 4 weeks of the best medical treatment
- No previous surgical treatment for correction of reflux
- No previous surgery for cutaneous self-grafting
- Presence of reflux directly overlying the ulceration site, which could be evaluated and documented with MEV and could be divided into isolated great saphenous reflux from incontinent saphenous or collateral axes; isolated superficial reflux from refluent perforating axes; and a combination of saphenous and perforators reflux (fig. 1).

Group A: controlled patients 226 - healed 206 (91,15%)
Group B: controlled patients 231 - healed 170 (73,59%)
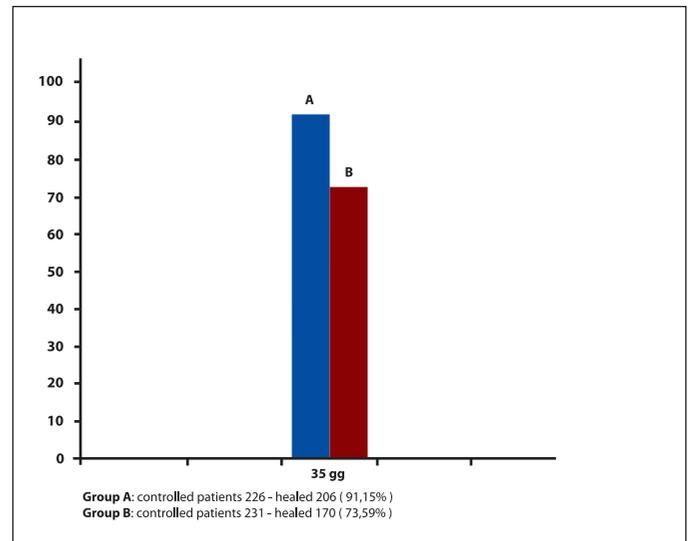
Fig. 3 - Global time of ulcers healing after surgical treatment (35 days).
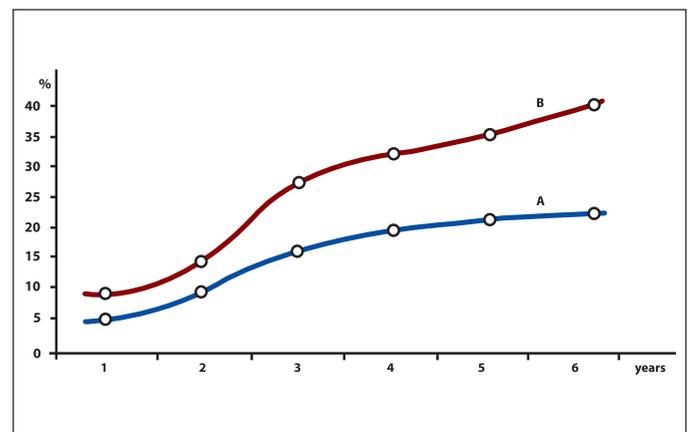
Fig. 4 - Recurrence of ulcers.

The types of medication previously taken by the patients (which had clearly been unsuccessful) were not considered. In almost all cases, patients were treated with "advanced medication," in particular with hydrocolloids, foams, and substances with enzyme activity. In Group A patients, EVLA was performed with a diode laser with a wavelength of 980 nm and 600 and 200 micron fibers with related catheters (EndoLaser Vein System ELVeS® from biolitec AG, Germany). The procedure was always performed under CD control with ESAOTE equipment and 7.5 MHz probes. Following percutaneous entry into the refluent vessel with the cannulation point located at the greatest possible distance from the dystrophic areas, the laser fiber was inserted into a guiding catheter and advanced until it reached the edges and the lower part of the lesion (fig. 2).

The same procedure was used in all cases. Echo-guided tumescent anesthesia was consistently used, with Marcaine and/or bland sedation. The energy emitted in pulses per vein cm, expressed in Joules, was adjusted in accordance with the characteristics of the vessel, diameter, and wall, by changing the power, time, and number of pulses.

Group B patients were treated surgically and/or with foam sclerotherapy according to standard criteria (fig. 3).

In the post-operative period and up to recovery, patients were treated with advanced medication according to the directions of the Consensus Document based on the individual characteristics of the lesions[14], by associating medical treatment with tested drugs[15] and elastocompression[16, 17]. Systematic antibiotic treatment was added in a minority of cases, with no significant difference between the two groups (7%).

The methods used to assess the healing and evolution of the ulcers were defined according to parameters and criteria that were previously proposed[18, 19].

Results

For all patients in both groups, we measured the amount of time it took for the lesions to heal completely after correction of the reflux (fig. 4). In both groups, we also evaluated the healing times for patients who, at the outset, had the same type of reflux: isolated saphenous reflux, isolated perforators reflux or combined saphenous and perforators reflux (fig. 5).
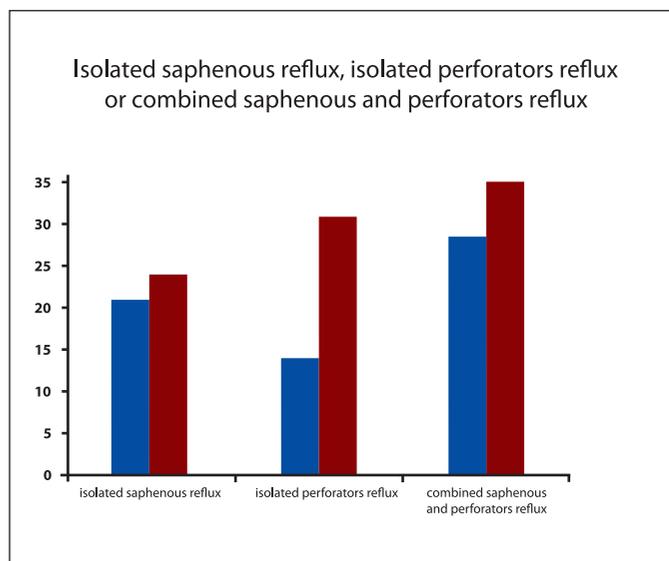
Fig. 5 - Healing times related to the same type reflux.

The prevalence of perforating vein reflux was high (42%) and comparable in both groups A and B. After recovery, patients attended annual follow-up appointments until December 2009 to evaluate the onset of a recurrence. Tests were conducted that were considered valid for 226 of the 280 patients in Group A and for 231 of the 280 patients in Group B. To sum up, the following aspects were evaluated:
 - Total recovery times for Groups A and B;
 - Healing times for each type of reflux corrected in Groups A and B;
 - Percentage of recurrences in Groups A and B after 1, 2, 3, 4, 5 and 6 years;
 - Type of reflux corrected in cases of recurrences found in Groups A and B with MEV upon examination.
Fig. 6 lists the percentages of recurrence detected in both Group A and Group B. With respect to the patients who suffered relapses, the same type of reflux and the hemodynamic condition that had existed at the outset emerged in each group upon recurrence of the ulcer. Subjective tolerance of the treatment and the level of satisfaction reported by the patients under treatment were also evaluated and found to be generally good, with patients expressing a greater preference for EVLA.

Discussion and conclusions
At present, there is little experience to draw on in terms of the treatment of and recovery from venous ulcers with the use of EVLA [12, 20-23]. In our opinion, EVLA and foam sclerotherapy presents a novel option for minimally invasive surgical treatment of lipodermatosclerosis with ulcers and is one that produces very interesting results. An analysis of our results leads us to draw the following conclusions. Overall healing times were shorter in Group A. Healing times were significantly shorter in Group A patients with isolated perforators reflux and combined saphenous/perforators reflux compared with similarly affected patients in Group B. On the other hand, no significant differences were found in the healing times for patients with isolated saphenous reflux in the two groups, regardless of whether the reflux was corrected with EVLA or with standard surgery/foam sclerotherapy. The percentage of total recurrences was lower in Group A. Almost all cases of recurrence, in both groups A and B, occurred in patients who had combined saphenous and perforators reflux when testing began.

The percentage of recurrences in patients who had saphenous and perforators reflux at the outset is clearly lower in Group A, while no significant differences were found between the two groups in patients with isolated saphenous reflux. Patients suffering a recurrence in both groups had superficial troncular reflux, either recurring after a previous treatment or presenting as new (absent at the outset). Another interesting data is the course of recurrence on time: while in fact group B has a constant increase of its percentage increment, in group A from year -4, this increment is much slower finally reaching a stabilization around years 5 and 6.
Based on these results, it can be reasonably claimed that the use of EVLA methods allows for a more effective correction of perforators reflux, in particular those sub-lesional "venous lakes" that cannot be directly accessed by open-sky surgery and respond poorly and inconsistently to sclerosing techniques [24]. In general, patients respond better to laser treatment than to foam sclerotherapy because of the different physical effect on the vessel wall, which undergoes thermo-constriction caused by dehydration with the laser[25]. This effect also persists in cases of recanalization, regardless of how the thrombotic component develops over time. The result is a lower hemodynamic involvement with respect to recanalization after sclerosis.
In conclusion, this data and our positive personal experiences of using EVLA, particularly in the subgroups with perforating vein reflux, leads us to expect that the correction of this reflux with minimally invasive laser surgery can be expected to heal most leg ulcers with primary CVI and reduce the recurrence of ulcers within the first three years after treatment. However, the value of such treatment for saphenous reflux alone remains unclear, although it is assumed that the elimination of saphenous reflux (e.g. high ligation or various forms of ablation) is key to diminishing the size of enlarged calf perforators[26].

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Effectiveness of the ELVeS 1470nm diode laser for leg ulcers ablation

Effectiveness of the EVLA 1470nm diode laser for leg ulcers ablation

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Since their inception in 1960, lasers have proved their effectiveness in various medical applications including ENT, vascular surgery, general surgery, dermatology, neurosurgery, etc. The laser use is reported to have beneficial effects on wound healing by stimulating the immune system, increasing various cytokines and leukocyte population, arresting bacterial growth, increasing the amount of total collagen and skin circulation and by accelerating the regeneration processes (1-7). In this study we used the new diode laser (Ceralas ELVeS 1470nm/15Watt) at the wavelength of 1470 nm in order to evaluate the effectiveness on foot and leg ulcers healing.

Materials

The diode laser Ceralas 1470nm (gallium arsenide semiconductor) was used for leg ulcer treatment. A low energy laser fluence was delivered on the ulcers through a 7 mm spot aiming to produce a photobiostimulation effect to reduce inflammation, enhance microvascular activity in order facilitate new tissue growth and accelerate the would healing process.

Patient selection

In the course of this study and from February 2009, until November 2009 we enrolled 20 patients, 10 males and 10 females, ages 38-87 years old, with one up to five ulcers/case, counting a total number of 36 ulcers. In the study included all forms of ulcers: venous, arterial-diabetic, neurotrophic and meta-traumatic and even patients with very deep ulcers, with tendon and small bones of the toes exposed. In addition, two of them had undergone plastic operation and unsuccessful "graft" covering of the ulcer. The size of ulcers was varying from 1 cm^2 up to 132 cm^2. From the total number of ulcers included (36), 9 were venous (superficial incompetence and metathrombotic syndrome), 8 were arterial (5 diabetic), 16 were neurotrophic and 3 traumatic. 23 ulcers were categorized as chronic (>6 weeks) and 13 as acute (<6 weeks).

Laser ablation

Laser ablation took once every 7-10 days. Before the laser session, all the ulcers were cleaned with normal saline or sterile water for injection and debrided from any necrotic tissues (especially at the first session). The ulcer area was measured before the start of every therapeutic session and images were taken before the start of every laser session.

The laser was set to 60 m sec. pulse duration, applying through a 7 mm spot an average fluence (energy) of 60 J/cm^2 on the wounds. The laser treatment was well tolerated and the energy fluence applied was varying (50-70 J/cm^2). For the niche treatment of the entire ulcerous area, a "tailor's" technique was used with point to point laser appliance, irradiating also an area of 1-2 cm out of the edges of the ulcers. After treatment, a hyaluronic acid jel (Jalplast) was used.

Analysis

For results evaluation we examined a) the progress and the level of the ulcer healing (closure) and b) the time/sessions required for the healing, and c) side effects.

Results

In conclusion, 77.7% of the venous ulcers, 62.5% of the neurotrophic ulcers, 87.5% of the arterial ulcers and 100% of the traumatic ulcers were completely closed. The average period until healing was 5.02 weeks (3-32 weeks). In detail, for venous ulcers it was 3.7 weeks (3-20 weeks), for neurotrophic ulcers it was 4.6 weeks (3-8 weeks), for arterial ulcers it was 7.7 weeks (3-32 weeks) and for traumatic ulcers it was 3.3 weeks (3-4 weeks). Of the 27 healed ulcers, 15 were chronic and 12 acute, which means that 65.2% of the chronic and 100% of the acute ulcers were completely healed (tab. 1).

Table 1: Results analysis for ulcers healing

Form of Ulcers	Number of Ulcers	Ulcers completely healed	Average Heal Period (Weeks)	Non Healed Ulcers
VENOUS	9	7 (77,7%)	3,7 (3-20)	2 (22,3%)
NEUROTROPHIC	16	10 (62,5%)	4,6 (3-8)	6 (37,5%)
ARTERIAL	8	7 (87,5%)	7,7 (3-32)	1 (12,5%)
TRAUMATIC	3	3 (100%)	3,3 (3-4)	- (-%)
TOTAL	**36**	**27 (75%)**	**5,02**	**9 (25%)**

Of the 9 ulcers that were not healed completely up to the end of the study we had analytically (tab. 2, 3):

Table 2: Summary analysis and healing progress of the 9 non healed ulcers

Duration of ulcer	Type of ulcer	Size of Ulcer (cm²)	Treatment time (weeks) progress of healing
10 years	venous	132 cm²	33 weeks/91% smaller
3 years	arterial	5,3 cm²	13 weeks/59% smaller
4 months	neurotrophic	23,4 cm²	3 weeks/32% smaller
4 months	neurotrophic	4,4 cm²	3 weeks/45% smaller
4 months	neurotrophic	25,5 cm²	3 weeks/30% smaller
3,5 months	neurotrophic	13,6 cm²	2 weeks/24% smaller
2 years	venous	78,12 cm²	3 weeks/76,5% smaller
8 months	neurotrophic	16,06 cm²	3 weeks/31,8% smaller
8 months	neurotrophic	5,76 cm²	3 weeks/29,7% smaller

Table 3: Summary analysis of the 27 headled ulcers

Duration of ulcer (pro-treatment)	Type of ulcer	Size of Ulcer (cm²)	Time to Healing (weeks)
4 years	VENOUS failed "graft" covering	52 cm²	20 weeks
4 weeks	VENOUS	2,4 cm²	3 weeks
4 weeks	VENOUS	4,6 cm²	4 weeks
6 weeks	VENOUS	5,7 cm²	3 weeks
4 weeks	VENOUS	5,2 cm²	3 weeks
5 weeks	ARTERIAL (with bone exposure)	4,9 cm²	32 weeks
4 weeks	VENOUS	4,5 cm²	3 weeks
5 weeks	NEUROTROPHIC	2 cm²	4 weeks
4 weeks	NEUROTROPHIC	1,7 cm²	3 weeks
3 weeks	ARTERIAL	1,8 cm²	3 weeks
2 weeks	ARTERIAL	2,5 cm²	3 weeks
4 weeks	ARTERIAL	2 cm²	3 weeks
8 weeks	ARTERIAL	9 cm²	5 weeks
12 weeks	NEUTROPHIC	1 cm²	2 weeks
10 weeks	NEUTROPHIC	2 cm²	2 weeks
2 years	VENOUS	3,8 cm²	4 weeks
2 weeks	TRAUMATIC	5,5 cm²	4 weeks
10 weeks	TRAUMATIC	4,5 cm²	3 weeks
9 weeks	TRAUMATIC	3,5 cm²	3 weeks
2 weeks	ARTERIAL	14,2 cm²	3 weeks
2,5 weeks	ARTERIAL	12,5 cm²	3 weeks
16 weeks	NEUTROPHIC	3,3 cm²	4 weeks
18 weeks	NEUTROPHIC	2,5 cm²	4 weeks
5 weeks	NEUTROPHIC	10,7 cm²	4 weeks
4 weeks	NEUTROPHIC	4,4 cm²	3 weeks
9 weeks	NEUTROPHIC	9,5 cm²	8 weeks
10 weeks	NEUTROPHIC	5,06 cm²	8 weeks

Discussion

The results of the study are very promising as the 75% of all the ulcers included in the study have completely healed. The closure rate was higher for acute ulcers than for the chronic ulcers.
A part from the progressive closure of ulcers, the ulcer related pain was significantly relieved after the first or second laser session, especially in arterial ulcers. No side effects were reported by the laser irradiation and the laser fluence at 50 Joules/cm was well tolerated by the patients.

Conclusions

The diode laser 1470nm as a source of photobiostimulation with a fluence of 60J/cm showed beneficial effect on wound healing by reducing inflammation, improving vascular activity and accelerating tissue growth and repair.
The diode laser 1470nm seems to be an effective, non-invasive, simple, painless and pain-relieving treatment with no reported side effects for the ulcer wound healing.

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J. O. López D'Ambola

Diode laser 1470nm for transdermal
treatment of varicose veins

Diode laser 1470nm for transdermal treatment of varicose veins

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The use of the 1470nm laser wavelength allows us to treat varicose veins transdermally in an effective and non-invasive manner, providing an ambulatory treatment method, without allergic reactions, easy to use and with a quick learning curve. The supplementary administration of an external chromophore which selectively absorbs light energy and transforms it into heat enhances the absorption coefficient for 1470nm and the development of the selective photo-thermolysis mechanism. Between November 2007 and November 2009, four hundred lower limbs with superficial venous insufficiency between 0.5 to 10mm in diameter and stratified according to CEAP classification as stages 2 to 6 were treated. Laser radiation energy form a 1470nm diode laser (ELVeS® PainLess, biolitec AG, Germany) was delivered transdermally in no-contact mode with the aid of a 1 and 7mm spot handpiece. Water was used as internal chromophore and hypertonic solution (ClNa 20%) was administered intravenously as external chromophore. All patients were evaluated with duplex ultrasound before, immediately and 7 days after treatment to assess the therapeutic outcome. During the treatment, a thermographic camera was used to assess the change of skin temperature in the treated area (Agema Thermovision 550 thermal imaging camera). The procedure was carried out in a non-surgical area, outpatient, in decubitus position, with no local or regional anesthesia. In the four hundred lower limbs treated, favorable clinical results were achieved. Thermal diffusion for this laser wavelength, with low powers and long pulse width is limited. A new laser wavelength for transdermal treatment of superficial venous insufficiency of the lower limbs is presented, associated to an external chromophore, ClNa 20%, giving objective and measurable results, which encourages us to move forward in this new therapy.

Introduction

This experience develops an effective, non-invasive, ambulatory treatment method, without allergic reactions, easy to use and with a quick learning curve. The use of the 1470nm laser wavelength allows us to reach greater depths with less scattering. It is assumed that radiation dispersion is inversely proportional to the wavelength and occurs mainly in areas rich in collagen when using small spot size and short laser wavelengths. Melanin has a low absorption coefficient for this wavelength. Following the selective thermolysis principles stated by Anderson Y. Parrish we should consider:
- the adequate wavelength that determines the selective absorption coefficient of the chromophore and the penetration depth;
- sufficient energy capable of damaging the target;
- thermal relaxation time (TRT) and pulse width.
However, in flat, spherical or cylindrical structures with irregular absorption characteristics, longer pulses with less energy can be used, avoiding unspecific collateral thermal damage.
The application of relatively low laser energy for a time period longer than TRT allows the dissipation of the absorbed heat, especially if the area has been previously cooled down. The chromophore selectively absorbs light energy and transforms it into heat which in turn diffuses to other regions with lower absorption coefficient causing additional thermal damage. Sodium chloride solution 20% is an osmotic agent that causes endothelial cell dehydration by disruption of cell water balance and also disrupts the non-cellular mural layers of the vessel with less index of re-channelization. It has complete absence of allergenic substances, cases of DVT-EP have not been described and tissue necrosis is infrequent. By increasing the concentration of saline solution inside the treated vessel, an enhanced absorption coefficient for 1470nm and the development of the selective photo-thermolysis mechanism is achieved (fig. 1).
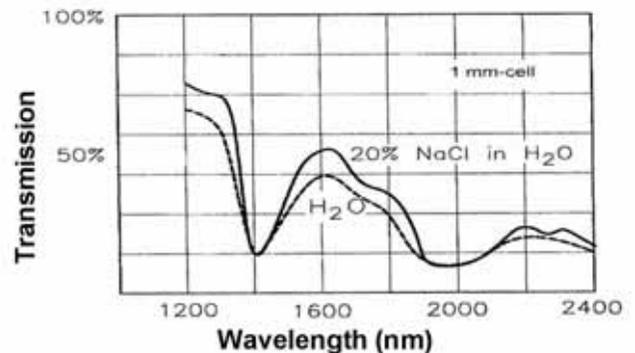
Fig. 1 - Photo-thermolysis mechanism.

Materials and methods

Four hundred lower limbs with superficial venous insufficiency between 0.5 to 10 mm in diameter and stratified according to CEAP classification as stages 2 to 6 were treated between November 2007 and November 2009. The following points were evaluated in the therapeutic protocol:
1) type of vascular lesion;
2) type of skin, according to Fitzpatrick ranking;
3) color venous echo-doppler images;
4) previous treatments: sclerotherapy, electrolysis and external RF;
5) concomitant skin lesions. The generation of a clinical history in general and phlebological history in particular, allows us to successfully establish the proper clinical diagnosis and classification into the corresponding CEAP stage. Laser radiation energy form a 1470nm diode laser (ELVeS® PainLess, biolitec AG, Germany) was delivered transdermally in no-contact mode with the aid of a 1 and 7mm spot handpiece, according to the diameter of the vein to be treated. Water was used as internal chromophore and hypertonic solution (ClNa 20%) was administered intravenously as external chromophore. All patients were evaluated with duplex ultrasound before, immediately and 7 days after treatment to assess the therapeutic outcome. During the treatment, a thermographic camera was used to assess the change of skin temperature in the treated area (Agema Thermovision 550 thermal imaging camera). The procedure was carried out in a non-surgical area, outpatient, in decubitus position, with no local or regional anesthesia. Firstly the area to be treated is externally cooled down by contact. Then, the varicose vein is punctured with a 30G needle and hypertonic sodium chloride solution is injected while immediately scanning the area with the laser handpiece in pulsed mode with pulse width of 20 to 40ms and 1 to 4W. This step is performed by moving the handpiece in a linear or V shaped movement, covering the largest possible area of the disease vessel. Elastic restraint of 8-15 mm Hg for 6 hours is indicated.

Results

In the four hundred lower limbs treated, favourable clinical results were achieved. With the thermographic images, it was found that the thermal diffusion for this laser wavelength, with low powers and long pulse width is limited. The photographic images allowed objectifying the results of the procedure and the subjective degree of compliance of patients about the procedure was highly satisfactory.

Conclusions

A new laser wavelength for transdermal treatment of superficial venous insufficiency of the lower limbs is presented, associated to an external chromophore, ClNa 20%, giving objective and measurable results, which encourages us to move forward in this new therapy.

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M. Gough

Postprocedure pain, safety and efficacy following great saphenous (GSV) Endovenous Laser Ablation (EVLA) using a 1470nm diode laser

Postprocedure pain, safety and efficacy following great saphenous (GSV) Endovenous Laser Ablation (EVLA) using a 1470nm diode laser

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ABSTRACT

Aims

EVLA abolishes GSV reflux and is an alternative to surgery for treating varicose veins. Currently lasers of 810-980nm wavelength (peak absorption by haemoglobin) are used.
Both direct vein wall contact and steam derived from intra-luminal blood may facilitate ablation. Despite its minimally invasive nature post-procedure pain was similar to that for surgery in a recent RCT. We have therefore assessed pain scores (and safety and efficacy) after GSV EVLA using a 1470nm diode laser (energy absorption by water in vein wall 40x >haemoglobin).

Methods

GSV ablation (ultrasound, 6 weeks), post-operative pain (100 mm linear analogue scale, days 1-7) and complications were assessed in patients treated with either an 810nm laser (Group A: n=29) or a 1470nm laser (Group B: n=22).

Results

Both groups received 60J/cm laser energy (median) with complete GSV occlusion achieved in 26/29 legs (90%, Group A) and 22/22 (100%, Group B) respectively. In Group A 2/29 (7%) patients developed temporary saphenous nerve paraesthesia (resolved by 6 weeks) and 3 (10%) significant "phlebitis". No complications occurred in Group B. Median pain scores (days 1-7) were 41, 20, 19, 8, 11.5, 14.5, 15 for Group A and 1, 0.5, 0, 0, 0.5, 1 for Groups B respectively (P<0.001 for all days).

Conclusions

GSV EVLA using a 1470nm diode laser is safe and effective. Furthermore patients experienced minimal post-procedure discomfort compared to those treated with the current generation of lasers. This may reflect more specific vein wall injury secondary to the absorption characteristics of the laser energy.

Endovenous laser ablation (EVLA) is a promising minimally invasive treatment with recent studies confirming short term results comparable to surgery. It is a safe procedure and serious complications are rare. However a significant number of patients experience post-procedure pain and bruising with phlebitis occurring in up to 30%. Although the technique and components of procedure are becoming standardised, there is considerable variation in the laser wavelengths used. There are few studies comparing wavelengths however, those published indicate there may be less bruising and a lower requirement for analgesia in those treated with longer wavelengths.

A possible explanation for the improved results is related to the absorbance profile of haemoglobin and intra cellular water. The wavelength of the current generation of laser (810-980nm) mainly target haemoglobin whereas longer wavelengths are absorbed up to forty-fold more by water, potentially producing greater tissue penetration. The aim of this study was to ascertain whether laser wavelength influenced outcome post EVLA for truncal vein incompetence.

Methods

A prospective study was performed in patients with primary varicose veins secondary to great saphenous vein reflux. Those suitable for EVLA underwent consultant led treatment using either an 810 (Group A) or 1470nm (Group B) continuous diode laser. In out-patients, under local anaesthetic, the GSV was cannulated under ultrasound guidance. The guide wire was placed and the catheter tip advanced to within 1-2cm of the sapheno-femoral junction. All patients received tumescent anaesthesia. The laser fibre was then inserted into the catheter and slowly withdrawn, delivering continuous laser energy at a rate of 2mm/sec, aiming to deliver a minimum of 60J/cm. Upon completion a foam sponge was positioned over the vein and compression bandage applied for 1 week followed by a further week of compression stockings. During the first week patients completed 100mm visual analogue scale for pain assessment on a daily basis. At 6 weeks post-procedure patients were clinically examined for evidence of complications and underwent ultrasound scanning at that point and a further scan at 3 months in order to identify abolition of GSV reflux. The primary end points were therefore pain score and GSV occlusion. Statistical analysis was performed using SPSS version 16.0.0 (Statistical package for Social Sciences Inc, Chicago, Illinois, USA). A p value ≤0.05 was considered statistically significant.

Results

Forty-nine patients were included in the study with 2 patients having received bilateral treatment.

There were more women in the study but there was no significant male female ratio difference between the two groups (p=0.378 Chi square test). The median age was 53 and patients treated had a CEAP score between 2 and 5. Both groups received median laser energy of 70J/cm. Group B had a 100% occlusion rate whilst in group A there was one failure to cannulate the GSV and 2 patients had a partially occluded GSV resulting in a 90% occlusion rate. Two patients in group A suffered transient saphenous paraesthesia and a further three had phlebitis. There were no complications in group B. Significantly lower pain scores were reported by patients treated with 1470nm (fig. 1).
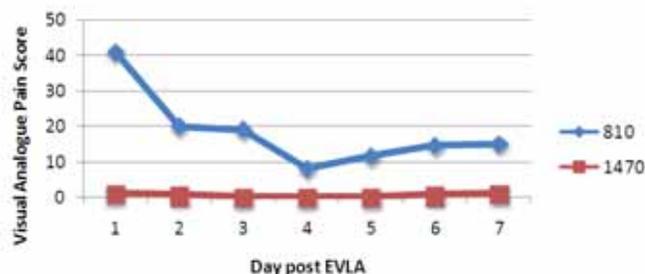
Fig. 1 - Post EVLA pain score (median) following treatment with 810 and 1470nm.

Conclusions

The results of this study confirm previous anecdotal reports that longer wavelength lasers are associated with less post-procedural pain than those currently used for EVLA.

Furthermore there were no complications in the 1470 group confirming its safety and all veins were successfully occluded. These results would be consistent with the hypothesis that the energy from the longer wavelength laser specifically targets the vein wall rather than causing thrombotic occlusion superimposed on irreversible vessel damage. A randomised control trial is being developed in order to confirm these apparent benefits.

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G. B. Agus

The hypothetical risk of Deep Venous Thrombosis (DVT) in Endovenous Laser Ablation (EVLA) of chronic venous insufficiency

The hypothetical risk of Deep Venous Thrombosis (DVT) in Endovenous Laser Ablation (EVLA) of chronic venous insufficiency

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ABSTRACT

The risk towards post operative DVT in varicose vein surgery is far less significant if compared to other surgeries. After surgical varicose therapy, a quick mobilization and correct elastic compression are to be considered the elective antithrombotic prophylaxis as widely disclaimed in the last decade Guide-lines and a wholesome review of 9 randomized controlled studies of elastic stocking efficacy alone and associated with other methods. Nevertheless, mismatching personal risk for DVT after individual control for thrombus risk factors, recent legal medical surveys for DVT, even lethal, have emerged. More precisely 0.02% for PE but up to 5.3% in cases of post surgical stripping DVT. In the past decade the problem was analysed for the new venous endovascular procedures. The International Debate has anyhow given the answers to the presumed thrombus risks in laser and radiofrequency treatments joined to the greatest case experience that reports DVT events between 0 and 0.5%.

Methods

A randomized controlled study on patients that underwent to day-surgery EVLA (Diode 980nm, ELVeS) of the greater saphenous was undertaken to compare heparin plus graduated elastic stockings with the only elastic stockings in the prophylaxis of DVT. One hundred same-risk patients for DVT were recruited. The stocking was worn for 4 weeks after surgery. The patients underwent duplex imaging before surgery, and at 3, 6 and 14 days after operation. All scans were performed by two of us.

Results and conclusions

The post operative Duplex control demonstrated adequacy of the elastic stocking and early mobilization as DVT prophylaxis without no cases of DVT in both groups.
The experience has emerged the following results:
a) family or personal history for DVT might require a limited blood coagulation screening and in patients with common DVT high risk factors, most of all when associated, heparin prophylaxis is appropriate;
b) safety of EVLA, if the guide catheter should be placed under Duplex scan control, better avoiding femoral introduction with the tip, below superficial epigastric connection, taking care that any eventual limb movement such as knee bending or hip abduction might introduce the fibre into the femoral vein;
c) higher Laser wavelength are safer;
d) anaesthesia already has a prophylaxis role: on one hand, local tumescent anaesthetic procedure allows immediate mobilization and, on the other, assures that the saphenous vein is collapsed onto the fibre in proximity to the SF junction;
e) lastly, the rare thrombotic complications so far reported may be due mainly to an insufficient learning curve.

Introduction

The risk towards post operative DVT in varicose vein surgery is far less significant if compared to other surgeries. The 8th ACCP Conference indeed asserts a low risk factor that disagrees with additional prophylaxis besides early mobilization (Grade 2B) reserving heparin therapy, either NFH or LMWH, exclusively for additional risk patients (Grade 1C+)[1].

After surgical varicose therapy, a quick mobilization and correct elastic compression are to be considered the elective antithrombotic prophylaxis as widely disclaimed in the last decade Guide-lines and a wholesome review of 9 randomized controlled studies of elastic stocking efficacy alone and associated with other methods[2-5]. Nevertheless, mismatching personal risk for DVT after individual control for thrombus risk factors, recent legal medical surveys for VTE, even lethal, have emerged. More precisely 0.02% for PE but up to 5.3% in cases of post surgical stripping DVT[6]. In the past decade the problem was analysed for the new venous endovascular procedures with ambiguous words as caution and as potential complication [7, 8].

Methods

Between September 2004 and September 2005, in the Section of Vascular Surgery and Angiology of the Department of Specialist Surgical Sciences at the University of Milan a randomized controlled study on patients that underwent to day-surgery EVLA (Diode 980nm, ELVeS) of the greater saphenous was undertaken to compare heparin plus graduated elastic stockings with the only elastic stockings in the prophylaxis of DVT. One hundred consecutive same-risk patients for DVT were recruited. After informed consent was obtained, the stocking was worn for 4 weeks after surgery in all patients, but heparin (LMWH) prophylaxis was administered in only fifty patients. The patients underwent duplex imaging before surgery, and at 3, 6 and 14 days after operation. All scans were performed by two of us.

Results

The post operative Duplex control demonstrated adequacy of the elastic stocking and early mobilization as DVT prophylaxis without no cases of DVT in both groups. LMWH can be used selectively in this group of patients and kind of Laser treatment.

Discussion

In the past decade the problem, analysed as effective possible event and cost-benefit of different prophylaxis methods, has been widely discussed. DVT exist in varicose vein surgery too, and this within a Duplex controlled post surgical prospectic study in absence of PE and over 50% asymptomatic patients[6]. Obesity and oral contraceptive therapy didn't seem to increase risk factors after surgery of the veins[6]. On this matter, a study carried out in the past by the Vascular Surgical Society of Great Britain and Ireland emerged that only 29% of surgeons consider, as attitude, DVT risk in surgery of the veins and only 12% employ post operative heparin prophylaxis[9].

Again in UK, after all, legal medical cases in the past decade for post surgical DVT appeared in only 8 out of 349 notified cases[10]. A prospective study on patients that underwent to day-surgery stripping of the greater saphenous vein with post operative Duplex control, demonstrated adequacy of the elastic stocking and early mobilization as DVT prophylaxis. Moreover, VTE cases may occur any day up to 34 days after the procedure and thus showing the uselessness of a 4 day prophylaxis aimed to reduce patient inconvenience and also limit National Health costs[11].

A retrospective study carried out on two groups of patients with and without post surgical Duplex control and use of different types of heparin as prophylaxis, once again confirms the low rate for VTE risk in varicose surgery, not too different from a common population for both sex and age[12].

A French study with an emblematic title "Faut-il vraiment prescrive des anticoagulants après chirurgie d' exérèse des varices?", considered over 4200 surgical procedures between January 1995 and December 2002 where only 0,40% of symptomatic DVT cases were found with only one PE (0.002%). The systematic pharmaceutical heparin prophylaxis and waste of millions of Euro is thus useless in the majority of operated cases, without diminishing the thrombotic risk[13].

Within a risk-benefit and cost-benefit analysis, Mildner reports 40% after surgery complications with heparin use against 7% without[14]. Only a Russian study, with however concept limits, supports necessity for routine LWMH prophylaxis. The calculated risk being for 0.07% and therefore not considering NNT. The layout of the prophylaxis scheme was for only the first 4 days when 0.38% of DVT occurred between 4th and 30th day subsequent to surgery leading to a no evidence based 1mg/kg aspirin 30 day prescription after surgery[15].

The low risk for VTE in conventional varicose surgery has partially suffered, as described in two works[7, 8], the new venous

endovascular procedures. The International Debate has anyhow given the answers to the presumed thrombus risks in Laser and RF treatments[16-18] joined to the greatest case experience that reports VTE events between 0 and 0,5%[19, 20]. Lastly, it must be said that a less active Laser wavelength (940-980, 1470nm) on haemoglobin and more on vein-wall water undoubtly even more reduce thrombosis risks.

Conclusions

The experience has emerged the following results:
a) family or personal history for DVT might require a limited blood coagulation screening and in patients with common DVT high-risk factors, most of all when associated, heparin prophylaxis is appropriate;
b) safety of EVLA, if the guide catheter should be placed under Duplex scan control, better avoiding femoral introduction with the tip, below superficial epigastric connection, taking care that any eventual limb movement such as knee bending or hip abduction might introduce the fibre into the femoral vein;
c) higher Laser wavelength are safer;
d) anaesthesia already has a prophylaxis role: on one hand, local tumescent anaesthetic procedure allows immediate mobilization and, on the other, assures that the saphenous vein is collapsed onto the fibre in proximity to the SF junction;
e) lastly, the rare thrombotic complications so far reported may be due mainly to an insufficient learning curve.

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FINAL REMARKS

J. Mauriello

Endovenous Laser Ablation of Varicose Veins:
Where are we going?

FINAL REMARKS

Endovenous Laser Ablation of Varicose Veins: Where are we going?

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Introduction

Since 1999 endovenous venous ablation (EVLA) has revolutionized how we treat reflux of the saphenous trunks in the United States. This also appears to becoming a similar reality in most of the world. We have witnessed a dramatic decrease in the number of ligation and strippings along with an incremental increase in the number of interventions utilizing endovenous thermal techniques (tab. 1). In just six years not only has surgery dropped from 93% to 5% of the number of procedures performed but the total number of procedures has tripled. Endovenous laser ablation (EVLA) is clearly the most performed treatment for varicose veins in the US and now accounts for more than 70% of all procedures. Why are more patients requesting treatment and doctors offering that service? It's gentle for the patient and rewarding for the physician. Never before have we been able to treat venous patients in such a simple way with such positive medical and esthetic results. Under local anesthesia patients are treated in outpatient settings with minimal invasion, short duration, and ambulatory recovery with an immediate return to normal activities. This is definitely a major improvement when compared to the previous treatments available for superficial venous insufficiency (SVI) yielding exceptional efficacy and superior patient satisfaction[1]. EVLA will join compression, the CEAP classification, and ultrasonography as the most significant advancements in the treatment and diagnosis of chronic venous insufficiency (CVI) in the past 20 years.

Endovenous Radiofrequency Ablation

Endovenous radiofrequency ablation (RFA) has been approved in the US since 1999 for the treatment of CVI and refluxing saphenous veins. Using a radiofrequency generator and special catheter, heat energy is produced by RF currents flowing through the patient's vein wall tissue. This heats the vein wall to 85-900 C causing venous spasm and collagen shrinkage resulting in vessel occlusion and eventual involution[2]. RFA has demonstrated excellent results being comparable to or better than traditional surgery[3-5]. Its major drawback was the slow manual continuous drawback of the catheter at 2-3 cm/minute as compared to 2-3 mm/second for EVLA[6]. This drawback was overcome in 2007 with the introduction of the next radiofrequency Closure Fast (CLF) catheters. This new 7 F diameter CLF catheter consists of a 7 cm heating coil and a thermal sensor.

Year	Surgery	Percent	RFA
2002	152,520	93%	9,840
2005	140,000	43%	60,000
2008	25,000	5%	130,000

Percent	EVLA	Percent	Totals
6%	1,640	1%	164,000
18%	120,000	37%	320,000
26%	340,000	68%	495,000

Tab. 1: Millennium Research Group. Market Growth: number of US procedures of varicose veins.

- **Wavelengths:** 808, 810, 940, 980, 1064, 1319, 1320, 1470, 1500

- **Type of laser:**
  Diode: 808, 810, 940, 980, 1470, 1500
  Nd:YAG: 1064, 1319, 1320

- **Dominant chromophore**
  Hemoglobin: 808, 810, 940*, 980* (HSLW)
  Water: 1064*, 1319, 1320, 1470, 1500 (WSLW)

Tab. 2: Current EVLA technology.

The coil at the tip of the catheter heats up to 1200 C for 20 seconds before the catheter is pulled back 6.5 cm to heat the next segment. CLF has turned RFA into a segmental thermal ablation procedure. For large diameter veins the segmental ablation can be repeated once or twice at the same site to ensure occlusion. If you look at energy density instead of temperatures, a single treated segment would equate to linear endovenous energy density (LEED) values of 68 J/cm and 116 J/cm for a double treated segment[7]. Long term occlusion rates of RFA of the GSV has been reported to be between 85-90%[8]. This has been shown to be less than EVLA[9]. However, with this new CLF catheter short term ablations rates are about 100% and long term efficacy of 3-5 years may approach that of EVLA.

Endovenous Laser Ablation
The first clinical trials using an 810nm diode laser showed unprecedented rates of great saphenous thermal ablation[10, 11]. Similar results with other diode lasers utilizing the 940nm and 980nm wavelengths were also reported[12]. With proper energy dosing, successful ablation of saphenous trunks are possible with any of these hemoglobin-specific laser wavelengths (HSLW). A prospective randomized trial compared the effects of the two wavelengths of 810nm and 980nm at equivalent LEED[13]. The 810nm wavelength is specific for hemoglobin while the 980nm wavelength targets mainly hemoglobin and to a lesser degree water. No major clinical differences were reported that would demonstrate one wavelength superior to the other in treating GSV insufficiency. Reported side effects did differ, with the 980nm group having statistically less bruising at 1 week post procedure, as well as lower pain levels at 4 months.
It has been well documented that EVLA with hemoglobin targeted lasers have more post procedural short term side effects (pain and bruising) then RFA[14, 15]. The RECOVERY study prospectively compared CLF to a HSLW at 980nm in a randomized, single-blinded multicenter study[16]. CLF was associated with improved recovery and quality-of-life parameters compared to the 980nm HSLW. All scores referring to pain, ecchymosis, and tenderness were statistically lower in the CLF group at 48 hours, 1 week, and 2 weeks. Attention has recently been focused on the utility and efficacy of water-specific laser wavelengths (WSLW) of 1.319, 1.320 & 1.470nm in management of SVI (tab. 2).

Fig. 1 - A 360 degree radial emitting fiber.
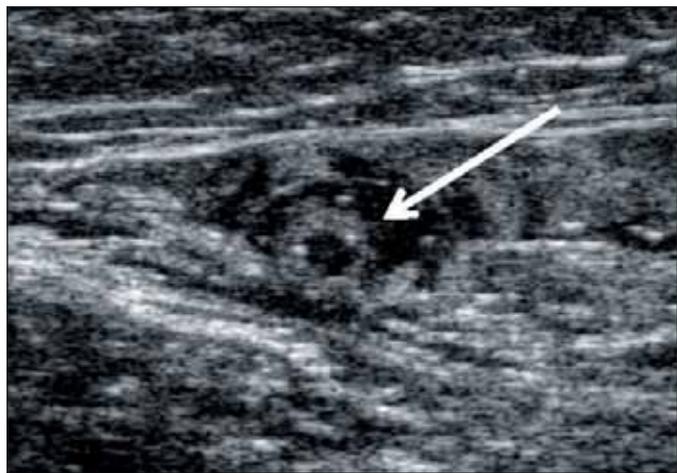
Fig. 2 - Post treatment vein wall changes.

It has been suggested that higher wavelengths may be efficacious in ablating incompetent saphenous veins, using less energy while minimizing procedural pain and bruising compared to conventional EVLA with HSLWs[17].

In fact, HSLW lasers (shorter wavelengths) produce more short term side effects (pain, bruising) than WSLW lasers (longer wavelengths) at comparable LEED[18]. There was even less short term side effects with the 1320 nm WSLW laser at 5 watts then at 8 watts with the same LEED[18].

So wavelength and power must play a role in postoperative short term side effects. These postoperative side effects are most likely caused by laser induced vein wall perforation with extravasation of blood into the surrounding tissue. Perforations of the vein wall are more common with HSLWs, higher power (watts) and greater LEEDs[11].

We have reported our initial experience of low energy density laser ablation treatment of incompetent truncal veins with a WSLW at 1470 using a radial emitting fiber (fig. 1).

We retrospectively examined the first 50 saphenous veins we had treated. Our data showed that lower power and energy density (3-7 watts with a mean LEED of 25.9 J/cm) may be equally effective at ablating incompetent truncal veins, while significantly minimizing patient discomfort, and other potential complications[19]. Others have reported similar results[20].

The low power settings and lower energy dosing with this WSLW at 1470 is a major shift in what has already been established for effective treatment outcomes with hemoglobin targeted lasers which optimally require LEEDs > 80 J/cm[21].

Immediate post treatment sonographic vein wall changes suggest that the vein wall is acting as a strong chromophore of the 1470nm wavelength with the radial emitting fiber (fig. 2). This may explain why we have seen a decrease in the amount of perivenous local anesthesia required for this laser wavelength as compared to other ETA methodologies we have used.

Another study using the 1470nm laser at much higher power (15 and 25 watts) with high LEEDs (107 J/cm GSV and 129 J/cm SSV) reported pain and paresthesias of 7.6% at one year[22]. This demonstrated that water targeted wavelengths are similar to hemoglobin targeted wavelengths when used at high power settings and high energy dosing.

The same authors compared the same 1470nm laser with three different fiber tips: a bare tip, a jacket tip (capped so it does not touch the vein wall) and a radial emitting tip.

The vein diameter decreased 38% in the bare tip group (using

Fig. 3 - Type of Fiber tip.

a mean LEED of 97 J/cm), 55% in the jacket tip group (104 J/cm) and 40% in the radial tip with only a mean LEED of 77 J/cm[23]. Pain was also reported to be much less in the radial fiber group. This showed we have another variable to consider: the type of fiber tip (fig. 3). Note that the radial tip fiber has a blunt end which makes it easy to thread up the vein with no danger of vein perforation and it does not require long insertion sheaths of 25, 45 and 65 cm. Contact of the bare fiber tip with the vein wall can lead to perforations which are the cause of post treatment pain and bruising. Covering or capping the fiber tip will eliminate direct contact and thus eliminate perforations which should reduce short term side effects. Patients treated with a jacket-tip fiber had statistically less pain than those with a bare tip fiber while using the same laser wavelength at 980nm at the same power and comparable LEED[24].

We presented a prospective randomized single-blinded split-leg study which compared CLF treatment of one leg to a WSLW of 1470nm using a radial emitting fiber in the other leg. Patients had no other adjunctive treatments of ambulatory phlebectomy or sclerotherapy. Our results showed that; 74.3% of the patients had no pain with 25.6% reporting pain at 0.68 (1-10 scale), 70.25% had no bruising and 85.1% required no pain medication. Statistical analysis showed there was no difference between the groups[25]. This data shows that patient short term recovery and six month closure rates with the 1470nm

wavelength laser with a radial emitting fiber is equal to that of radiofrequency CLF. Long term efficacy studies are needed to see if longer wavelengths at lower powesssr and LEEDs will equal that of HSLW using traditional settings milk.

What we know. The Present
Endovenous lasers have improved patient outcomes as compared to surgical vein stripping. Efficacy of EVLA is very high but no wavelength has been shown to be statistically superior with regard to long term closure rates. Patient post procedure recovery has improved with longer wavelengths targeting water and with capping or jacketing of fiber tips by eliminating bare tip fiber contact with the vein wall. Minimal effective energy densities (MEEDs) are not the same for HSLWs and WSLWs and may also vary with different fiber tips. It has taken ten years to get to this point and patients have benefitted immensely.

Where are we going? The Future
No doubt that EVLA will lead the thermal techniques in elimination of saphenous reflux. Can treatment outcomes be improved? In medicine nothing can be 100% effective and we are already at a very high rate of success with saphenous ablation. Recurrences will always occur because we are confronting a slow progressing problem. Will wavelengths get longer, moving toward the last peak of water absorption at near-infrared wavelengths of 2.000nm? Will fiber tips change? Will further studies lead to establishing MEEDs for different combinations of fiber tips, wavelengths and power settings? I'm sure, but it will not take another ten years.

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APPENDIX
(with permission)

R. van den Bos

Endovenous therapies of lower extremity varicosities:
A meta-analysis

APPENDIX
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Endovenous therapies of lower extremity varicosities: A meta-analysis

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Background
Minimally invasive techniques such as endovenous laser therapy, radiofrequency ablation, and ultrasound guided foam sclerotherapy are widely used in the treatment of lower extremity varicosities. These therapies have not yet been compared with surgical ligation and stripping in large randomized clinical trials.

Methods
A systematic review of Medline, Cochrane Library, and Cinahl was performed to identify studies on the effectiveness of the four therapies up to February 2007. All clinical studies (open, noncomparative, and randomized clinical trials) that used ultrasound examination as an outcome measure were included. Because observational and randomized clinical trial data were included, both the Meta-analysis of Observational Studies in Epidemiology (MOOSE) and Quality of Reporting Of Meta-analyses (QUORUM) guidelines were consulted. A random effects meta-analysis was performed, and subgroup analysis and meta-regression were done to explore sources of between study variation.

Results
Of the 119 retrieved studies, 64 (53.8%) were eligible and assessed 12,320 limbs. Average follow-up was 32.2 months. After 3 years, the estimated pooled success rates (with 95% confidence intervals [CI]) for stripping, foam sclerotherapy, radiofrequency ablation, and laser therapy were about 78% (70%-84%), 77% (69%-84%), 84% (75%-90%), and 94% (87%-98%), respectively. After adjusting for follow-up, foam therapy and radiofrequency ablation were as effective as surgical stripping (adjusted odds ratio [AOR], 0.12 [95% CI, - 0.61 to 0.85] and 0.43 [95% CI, - 0.19 to 1.04], respectively). Endovenous laser therapy was significantly more effective compared with stripping (AOR, 1.13; 95% CI, 0.40-1.87), foam therapy (AOR, 1.02; 95% CI, 0.28-1.75), and radiofrequency ablation (AOR, 0.71; 95% CI, 0.15-1.27).

Conclusions
In the absence of large, comparative randomized clinical trials, the minimally invasive techniques appear to be at least as effective as surgery in the treatment of lower extremity varicose veins. (J. Vasc. Surg. 2009; 49:230-9).

Lower-extremity venous insufficiency is a common medical condition and occurs in about 15% of men and 35% of women[1-3]. The effect of venous insufficiency on patients' health-related quality of life (HRQOL) is substantial and comparable with other common chronic disease[4]. In 1995 the overall cost associated with deep or superficial venous insufficiency, or both, was about 2.5% of the total health care budget in France and Belgium[5]. The treatment of varicose veins alleviates symptoms and, hopefully, reduces the complication rate of venous insufficiency. The traditional gold standard in the treatment of varicosity of great saphenous veins (GSVs) is a high ligation at the saphenofemoral junction (SFJ), followed by stripping; conventional treatment of small saphenous veins (SSVs) is ligation at the saphenopopliteal junction (SPJ), often without stripping. Surgery of varicose veins is usually performed under general or epidural anesthesia and may be associated with neurologic damage (about 7% in short and up to 40% in long stripping of GSVS),[6,7] scars, and postoperative pain. Despite the relatively high incidence, the neurologic damage has often Little resultant morbidity. Although surgery is highly effective in the short term, the 5-year recurrence rates are approximately 30% for GSVs and 50% for SSVs, which may be due to neovascularization[8,9]. Only <10% of these recurrences are clinically relevant. To improve effectiveness and patients' HRQOL and to reduce postoperative downtime, complications, and costs, new minimally invasive techniques such as ultrasound-guided foam sclerotherapy (UGFS),[10] radiofrequency ablation (RFA, VNUS Closure, VNUS Medical Technologies, San Jose, Calif),[11] and endovenous laser ablation (EVLA)[12] are now widely used in the treatment of lower extremity varicosities. Although case series and comparative studies suggest lower recurrence rates of these minimally invasive interventions compared with surgical stripping, no large, long term, comparative randomized controlled trials (RCTs) have been performed yet, but some are ongoing[13]. The objective of this analysis is to systematically review and summarize the available studies on the surgical and new therapies and compare the effectiveness of these different options in order to assist physicians and patients in selecting the most appropriate intervention for lower extremity varicose veins in the current absence of well-designed RCTs.

Methods

Because of the heterogeneity of the included studies, both the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) and Quality Of Reporting Of Metaanalyses (QUORUM) guidelines were used[14, 15].

Literature search. We initiated an electronic search of Medline, Cochrane Library, and Cinahl up to February 2007. PubMed was searched by a clinical librarian using the following algorithm: (sclerocompression or sclerotherapy) or ([{thermal or radiofrequency} and {ablation or obliteration}] or VNUS) or (laser or laser surgery) or (endovascular or endovenous) or (stripping or stripped or strip or strips or stripper or Babcock)

and (saphenous or saphena or varicose veins or varicosis) and (duplex or Doppler or ultrasonic or ultrasound). To broaden the search, the "related articles" function was also used. Specialty journals such as Derma-tologic Surgery, Journal of Vascular Surgery, European Jour-nal of Vascular and Endovascular Surgery, and Phlebology were also searched electronically and references of identified studies and reviews were hand-searched. We reviewed all abstracts, studies, and citations, irrespective of language. Clinical trial registries were also searched.

Inclusion criteria. Our meta-analysis included RCTs, clinical trials, and prospective and retrospective case series on the treatment of human lower extremity varicosities by surgical stripping (SFJ ligation and GSV stripping or SPJ ligation [and SSV stripping]), EVLA (all wavelengths and energy parameters were included), UGFS with foam (multiple treatments were allowed and no distinction was made between type or concentration of sclerosant), and RFA.

We were unable to differentiate between GSVs and SSVs because most studies that included both did not differentiate the outcomes. Only studies that used US examination as the outcome measure were eligible because US is considered the gold standard in the assessment of venous insufficiency and it increases the homogeneity of the analysis. For comparative studies, the arms of interest were included separately. All follow-up periods were allowed. English, German, French, and Dutch studies were included.

Exclusion criteria. Studies that performed SFJ ligation without stripping were excluded because this approach is considered suboptimal[16]. Studies that explicitly examined combination therapies were excluded. Treatments of nontruncal varicose veins were not included. We excluded UGFS studies that used liquid sclerosant because it is considered less effective than foam[17]. To our knowledge, there are no comparative RCTs suggesting a type of sclerosant is superior in the treatment of saphenous trunks using UGFS. Moreover, a RCT showed no significant difference between polydocanol and sodium tetradecyl sulfate in the treatment of varicose and telangiectatic veins, suggesting that the effect of the specific sclerosant in our analysis is limited[18]. If multiple articles reported the same study population, the publication with the longest follow-up was included.

Data extraction. The data of all eligible studies were analyzed by two authors (R. v. d. B. and T. N.) independently. The number of patients and treated limbs, the type of veins (GSV or SSV), the treatment procedure, the study type (retrospective or prospective), the duration of follow-up, the type of follow-up (mean follow-up, exact follow-up, or exact with loss of follow-up), the US outcome definitions, and success rate (if possible for GSVs and SSVs separately) were recorded. Because 89% of the included studies were case series, an extensive quality assessment of the studies was not performed, except that a distinction was made between retrospective and prospective data collection. Case series and the arms of interest of RCTs were entered separately in the analysis.

Standardization of outcome measures. All of the eligible studies

Table 1: Characteristics of studies included in meta-analysis

No.	First author	Year[a]	Country	Study type[b]	Total	GSV	SSV	Therapy	Follow-up[c]	Total	GSV	SSV	Definition of failure
					No. of included limbs					Success rate			
1	Allegra	2007	Italy	1	1326	862	132	Surgery	60	0.75	0.87	0.7	Recurrent/new varices
2	Bountouroglu	2006	UK	3	30	30	0	Surgery	3	0.78	0.78	NA	Closed/occlusion/ obliteration
3	De Maseneer	2002	Belgium	1	172	172	0	Surgery	12	0.75	0.75	NA	Recurrent/new varices
4	De Medeiros	2005	Brazil	3	20	20	0	Surgery	1	1.00	1.00	NA	Re-opening
5	Dwerryhouse	1999	UK	1	52	52	0	Surgery	60	0.5	0.5	NA	Recurrent/new varices
6	Fischer	2001	Swiss	2	125	125	0	Surgery	408	0.4	0.4	NA	Recurrent/new varices
7	Frings	2004	Germany	1	500	500	0	Surgery	3	0.95	0.95	NA	Detectable flow/ reflux
8	Hartmann	2006	Germany	2	245	220	25	Surgery	168	0.69	0.66	0.88	Recurrent/new varices
9	Hinchliffe	2006	UK	3	16	16	0	Surgery	1.5	0.88	0.88	NA	Incomplete strip
10	Lurie	2005	USA	3	36	36	0	Surgery	24	0.79	0.79	NA	Recurrent/new varices
11	Perala	2005	Finland	3	13	13	0	Surgery	36	0.77	0.77	NA	Recurrent/new varices
12	Sarin	1994	UK	2	43	43	0	Surgery	21	0.51	0.51	NA	Detectable flow/ reflux
13	Smith	2002	UK	1	226	189	37	Surgery	12	0.86	0.91	0.62	Detectable flow/ reflux
14	Barrett 1[a]	2004	NZ	2	99	79	20	UGFS	23.7	0.69	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
15	Barrett 1[b]	2004	NZ	2	17	14	3	UGFS	24.5	0.77	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
16	Barrett 2	2004	NZ	2	100	98	23	UGFS	22.5	0.77	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
17	Belcaro 1[e]	2000	Italy	3	39	39	0	UGFS	120	0.81	0.81	NA	Detectable flow/ reflux
18	Belcaro 2[e]	2003	Italy	3	211	211	0	UGFS	120	0.49	0.49	NA	Recurrent/new varices
20	Darke	2006	UK	1	143	115	28	UGFS	1.5	0.88	0.86	0.96	Closed/occlusion/ obliteration
21	Hamel-Desnos	2003	France	1	45	45	0	UGFS	0.75	0.84	0.84	. . .[d]	Detectable flow/ reflux
19	Smith	2006	UK	1	1411	886	263	UGFS	11	0.86	0.88	0.82	Closed/occlusion/ obliteration
22	Tessari	2001	Italy	1	24	9	7	UGFS	1	1	1	1	Closed/occlusion/ obliteration
23	Yamaki	2004	Japan	1	37	37	0	UGFS	12	0.68	0.68	NA	Closed/occlusion/ obliteration
24	Agus	2006	Italy	1	1068	1052	16	EVLA	36	0.97	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
25	De Medeiros	2005	Brazil	1	20	20	0	EVLA	2	0.95	0.95	NA	Closed/occlusion/ obliteration
26	Disselhoff	2005	Netherlands	1	93	93	0	EVLA	3	0.84	0.84	NA	Closed/occlusion/ obliteration
27	Gerard	2002	France	1	20	20	0	EVLA	1	0.9	0.9	NA	Closed/occlusion/ obliteration
28	Gibson	2007	USA	1	210	156	210	EVLA	4	0.96	NA	0.96	Recanalization
29	Goldman	2004	USA	1	24	24	0	EVLA	8	1	1	NA	Detectable flow/ reflux
30	Huang	2005	China	1	19	19	0	EVLA	0.5	1	1	NA	Closed/occlusion/ obliteration
31	Kabnick	2006	USA	1	60	60	0	EVLA	12	0.93	0.93	NA	Detectable flow/ reflux
32	Kavuturu	2006	USA	1	66	66	0	EVLA	12	0.97	0.97	NA	Closed/occlusion/ obliteration
33	Kim 1	2006	USA	1	34	34	0	EVLA	12.2	1	1	NA	Recanalization

Table 1: Continued

No.	First author	Year[a]	Country	Study type[b]	Total	GSV	SSV	Therapy	Follow-up[c]	Total	GSV	SSV	Definition of failure
					No. of included limbs					Success rate			
34	Kim 2	2006	USA	1	60	60	0	EVLA	6.8	0.97	0.97	NA	Closed/occlusion/ obliteration
35	Marston	2006	USA	2	31	31	0	EVLA	0	0.84	0.84	NA	Closed/occlusion/ obliteration
36	Morrison	2005	USA	1	50	50	0	EVLA	12	0.66	0.66	NA	Closed/occlusion/ obliteration
37	Min 1	2001	USA	1	90	90	0	EVLA	9	0.96	0.96	NA	Closed/occlusion/ obliteration
38	Min 2	2003	USA	1	499	499	0	EVLA	24	0.93	0.93	NA	Closed/occlusion/ obliteration
39	Navarro	2001	USA	1	40	40	0	EVLA	4.2	1	1	NA	Detectable flow/ reflux
40	Oh	2003	Korea	1	15	15	0	EVLA	3	1	1	NA	Closed/occlusion/ obliteration
41	Perkowski	2004	USA	1	191	154	37	EVLA	0.5	0.97	. . .[d]	. . .[d]	Recanalization
42	Petronelli	2006	Italy	1	52	52	0	EVLA	12	0.93	0.93	NA	Recanalization
43	Proebstle 1	2002	Germany	1	31	31	0	EVLA	1	0.97	0.97	NA	Closed/occlusion/ obliteration
44	Proebstle 2	2003	Germany	1	41	41	0	EVLA	6	0.95	0.95	NA	Recanalization
45	Proebstle 3	2004	Germany	2	106	106	0	EVLA	3	0.9	0.9	NA	Closed/occlusion/ obliteration
46	Proebstle 4	2005	Germany	1	282	282	0	EVLA	3	0.98	0.98	NA	Closed/occlusion/ obliteration
47	Proebstle 5	2006	Germany	1	263	263	0	EVLA	12	0.96	0.96	NA	Closed/occlusion/ obliteration
48	Puggioni	2005	USA	2	77	77	0	EVLA	0.25	0.94	0.94	NA	Recanalization
49	Ravi	2006	USA	1	1091	990	101	EVLA	0.5	0.96	0.97	0.91	Recanalization
50	Sadick	2004	USA	1	30	30	0	EVLA	24	0.97	0.97	NA	Closed/occlusion/ obliteration
51	Sharif	2006	UK	1	145	145	0	EVLA	12	0.76	0.76	NA	Closed/occlusion/ obliteration
52	Theivacumar	2007	UK	1	68	0	68	EVLA	6	0.88	. . .	0.88	Closed/occlusion/ obliteration
53	Timperman	2005	USA	1	100	83	0	EVLA	9	0.96	0.96	NA	Detectable flow/ reflux
54	Dunn	2006	USA	1	85	85	0	RFA	6	0.9	0.9	NA	Closed/occlusion/ obliteration
55	Fassiadis	2003	UK	1	59	59	0	RFA	3	1	1	NA	Closed/occlusion/ obliteration
56	Goldman	2000	USA	1	12	12	0	RFA	6	1	1	NA	Closed/occlusion/ obliteration
57	Goldman	2002	USA	1	41	41	0	RFA	13	0.68	0.68	NA	Closed/occlusion/ obliteration
58	Hinchliffe	2006	UK	3	16	16	0	RFA	1.5	0.81	0.81	NA	Closed/occlusion/ obliteration
59	Hingorani	2004	USA	1	73	73	0	RFA	0.3	0.96	0.96	NA	Closed/occlusion/ obliteration
60	Lurie	2005	USA	1	46	46	0	RFA	24	0.86	0.86	NA	Recurrent/new varices
61	Marston	2006	USA	2	58	58	0	RFA	0	0.88	0.88	NA	Closed/occlusion/ obliteration
62	Merchant 1	2002	USA	1	318			RFA	24	0.85	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
63	Merchant 2	2005	USA	1	1222	1154	52	RFA	60	0.87	. . .[d]	. . .[d]	Closed/occlusion/ obliteration
64	Morrison	2005	USA	1	50	50	0	RFA	12	0.8	0.8	NA	Closed/occlusion/ obliteration
65	Ogawa	2005	Japan	1	25	25	0	RFA	1	1	1	NA	Closed/occlusion/ obliteration
66	Perala	2005	Finland	3	15	15	0	RFA	36	0.67	0.67	NA	Recurrent/new varices
67	Pichot	2004	France	2	63	63	0	RFA	25	0.91	0.91	NA	Closed/occlusion/ obliteration

Table 1: Continued

No.	First author	Year[a]	Country	Study type[b]	No. of included limbs			Therapy	Follow-up[c]	Success rate			Definition of failure
					Total	GSV	SSV			Total	GSV	SSV	
68	Puggioni	2005	USA	2	53	53	0	RFA	0.23	0.91	0.91	NA	Recanalisation
69	Sybrandy	2002	Netherlands	1	26	26	0	RFA	12	0.89	0.89	NA	Closed/occlusion/ obliteration
70	Wagner	2003	USA	2	28	28	0	RFA	3	1	1	NA	Closed/occlusion/ obliteration
71	Weiss	2002	USA	1	140	140	0	RFA	0	0.9	0.9	NA	Closed/occlusion/ obliteration
72	Welch	2006	USA	2	184	184	0	RFA	0	0.8	0.8	NA	Closed/occlusion/ obliteration

EVLA, endovenous laser ablation; GSV, great saphenous vein; NA, nonapplicable; NZ, New Zealand; RCT, randomized clinical trial; RFA, radiofrequency ablation; SSV, short saphenous vein; UGFS, ultrasound-guided foam sclerotherapy; UK, United Kingdom; USA, United States of America.
[a]Year of publication.
[b]Type 1 is prospective case series, type 2 is retrospective case series, and type 3 is a randomized clinical trial.
[c]Follow-up in months.
[d]Not documented separately for GSV and SSV.
[e]The surgery arm of this study was not included because only ligation without stripping was performed.

used US as an outcome, but the definitions of treatment success by US examination varied considerably. Because the technical end point of each of the treatments is obliteration or complete removal (i. e., anatomic success) of the insufficient vein, the definitions that closely reflected this objective were grouped by consensus of three authors (R. v. d. B., M. N., and T. N.). Therefore, US based outcomes that used definitions such as a bsence of "detectable flow," "recurrence of reflux," "recanalization," "vein reopening," "recurrent or new varices," "closed vein," "occlusion," "obliteration," and "completely stripped vein" were considered to be equally successful. Studies that reported "clinical improvement," "patient satisfaction," "reflux at any site," "varicose veins present any-where," and others were excluded.

Statistical analysis. After deriving the natural logarithm of the odds of success for all studies, we calculated pooled estimates of success rate and the 95% confidence interval (CI) for all four treatments using SAS PROC MIXED software (SAS Institute Inc, Cary, NC). A random-effect model[19-21] was used because a likelihood ratio test showed that the random-effect model fitted the data significantly better than did a fixed-effect model ($x^2_4 = 32.7$, $P < .001$). We compared a random-effect model with one general random intercept to a multivariate random-effect model in which each treatment has its own random intercept. Because the latter did not improve the model significantly ($x^2_3 = 3.8$, $P = .28$), we used the random-effect model with one general random intercept only for all treatments. The treatments were used as covariates in the model, and the differences between the estimated log odds of the treatments automatically resulted in the log odds ratios (OR) to compare the treatments with each other. Because follow-up time varied considerably within and between the four treatment groups and the decline of success percentages over time may differ per treatment, a meta-regression with follow-up time per treatment as a covariate was performed to present success rates for different time intervals (i. e., 3 months, 1, 3, and 5 years). Furthermore, we performed
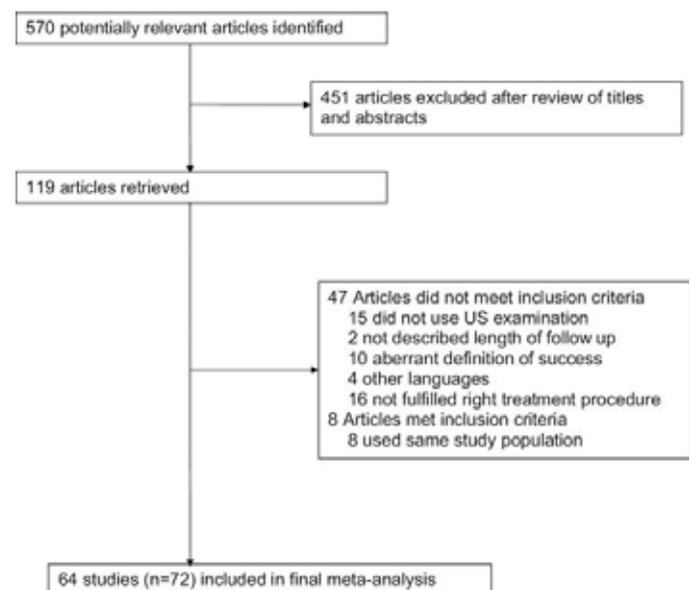
Fig. 1 - Schematic flow chart of literature search.

subgroup analysis based on the type of study (prospective vs. retrospective) and study size (more or less than 60 limbs). The between-study variances of the models with and without these covariates were compared to assess whether heterogeneity in the covariates can explain part of the between-study variances.

Results

Literature search. Of all screened abstracts and titles, 119 reports were reviewed in detail, and 64 studies (with a total of 72 arms) fulfilled the eligibility criteria. Of these, 13 (18%) reported on stripping, 10 (14%) on UGFS, 30 (42%) on EVLA, and 19 (26%) on RFA (tab. 1). We excluded 55 studies for several reasons (fig. 1).
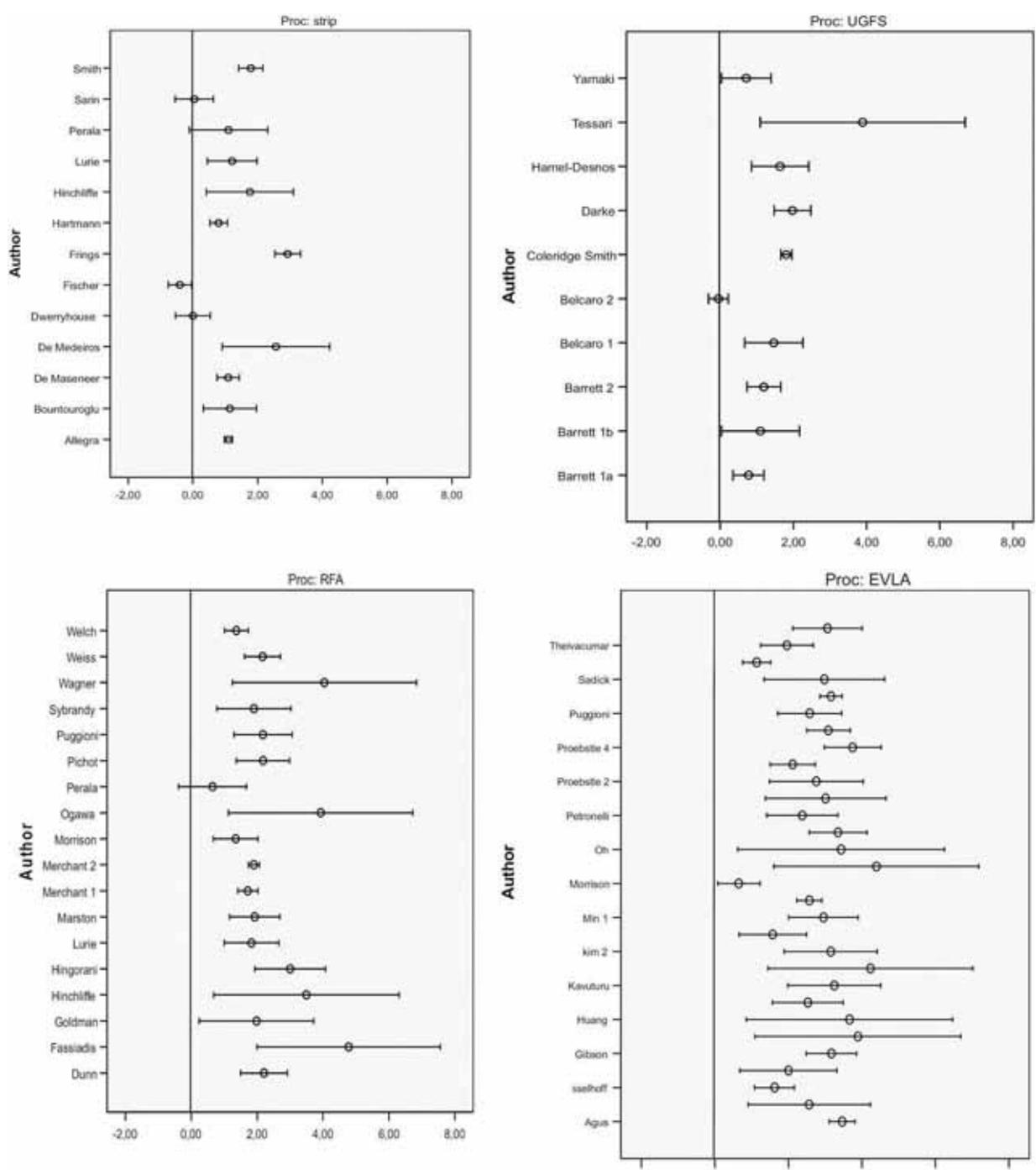
Fig. 2 - Forest plots with log(odds) of each study ordered per treatment.

Study characteristics for included trials. We included 64 studies (72 study arms) with a total of 12,320 treated limbs, of which 2804 (23%) were stripped, 2126 (17%) were treated by UGFS, 4876 (40%) by EVLA, and 2514 (20%) by RFA. The reports were published between January 1994 and February 2007, and 92% in the last 5 years (tab. 1). Of the 72 study arms, 58 (81%) were prospective. Although follow-up duration ranged from 1 day to 34 years, 51 of the 72 studies had a follow-up of between 3 months and 10 years. The number of included limbs was 12 to 1411. Nine studies reported the separate success rates of SSV and GSV therapy, and seven were RCTs that included two intervention arms. Nine of the 10 UGFS studies used aethoxysclerol (polydocanol), one study only used sodium tetradecyl sulfate, and three studies used both sclerosants.

Table 2: The pooled proportion of patients with anatomical successful outcome after different time intervals

	3 months		1 year		3 year		5 year	
Type of intervention	*Success rate (%)*	*95% CI*	*Success rate (%)*	*95% CI*	*Success rate (%)*	*95% CI*	*Success rate (%)*	*95% CI*
Surgery	80.4	72.3-86.5	79.7	71.8-85.8	77.8	70.0-84.0	75.7	67.9-82.1
UGFS	82.1	72.5-88.9	80.9	71.8-87.6	77.4	68.7-84.3	73.5	62.8-82.1
RFA	88.8	83.6-92.5	87.7	83.1-91.2	84.2	75.2-90.4	79.9	59.5-91.5
EVLA	92.9	90.2-94.8	93.3	91.1-95.0	94.5	87.2-97.7	95.4	79.7-99.1

CI, ConÏdence intervals; *EVLA,* endovenous laser ablation; *RFA,* radiofrequency ablation; *UGFS,* ultrasound guided foam sclerotherapy.
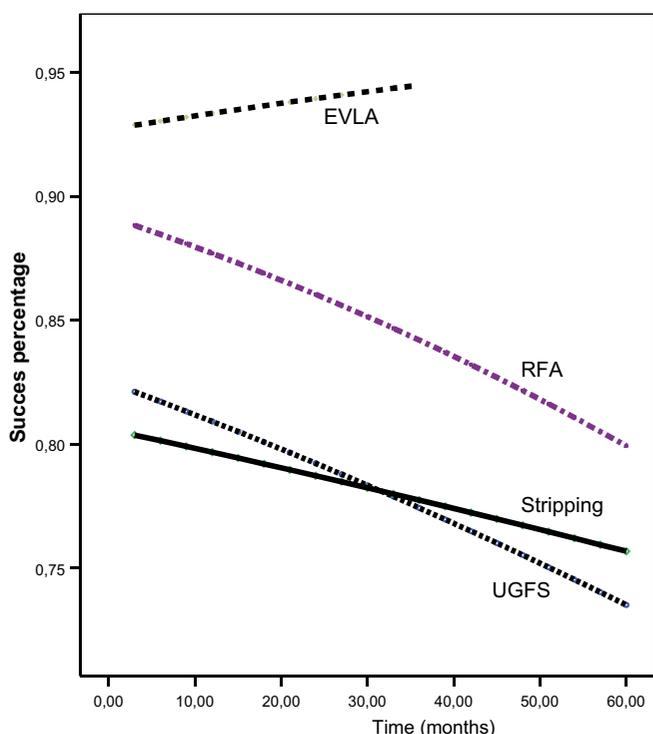
Success rates for each therapy. The crude success rates of each of the four therapies independent of follow-up time according to the random-intercept model suggest that the success rate of EVLA (93.3%; 95% CI, 91.0-95.0) and RFA (87.5%; 95% CI, 82.5-91.3) are higher than for stripping and UGFS (fig. 2). For stripping, UGFS, and RFA, the effectiveness of the therapies decreased over time from ≥80% success rates at 3 months to <80% after 5 years. The success percentages of EVLA remained at ≥92.9% (tab. 2, fig. 3). The estimated success rates declined significantly for stripping (*P* = .004), but no significant negative trend was detected for UGFS (*P* = .08), RFA (*P* = .25), or EVLA (*P* = .61) over time.

Comparison of therapies. Compared with stripping, UGFS was as effective and EVLA and RFA were significantly more effective in the treatment of lower extremity varicose veins (tab. 3). After adjusting for duration of follow-up, however, we observed no significant differences between stripping and RFA. Of the three minimally invasive techniques, EVLA was superior to UGFS (*P* = .013) and RFA (*P* = .016) after adjusting for follow-up time, but .0001), and RFA (*P* = .01).

Subgroup analysis. Restricting the analysis to the 58 prospective studies confirmed that EVLA was significantly more effective than stripping (*P* < .0001), UGFS (*P* < .0001), and RFA (*P* = .01). However, no significant differences in effectiveness were observed between RFA vs. stripping (*P* = .14) and RFA vs. UGFS (*P* = .13). The results of the analyses of the 35 largest studies that treated >60 limbs were comparable with the complete meta-analysis: EVLA remained significantly more successful than stripping (*P* < .0001), UGFS (*P* < .0001), and RFA (*P* = .04); and RFA was superior to stripping (*P* = .048) and UGFS (*P* = .04). Excluding the SSV and restricting the analysis to 62 studies that presented success rates for GSVs (separately) confirmed the finding that EVLA was significantly more effective than the other therapies (*P* < .0001).

Discussion
The results of this meta-analysis suggest that endovenous treatments of lower extremity varicosities are better in achieving anatomic success (i. e., obliteration or disappearance of veins) than surgery and UGFS. Of the endovenous therapies, EVLA is significantly more effective than RFA to obliterate the insufficient veins. These findings, however, should be confirmed in large, long-term, comparative RCTs.

The estimated success rates of the studied therapies and the comparison between therapies are in agreement with most of the available studies. A small paired analysis[22] and a nonrandomized pilot study that compared EVLA with stripping of the GSV[23] showed that the clinical efficacy parameters were comparable in the short term. A recent RCT showed that EVLA was as effective as stripping after 6 months and was associated with less postoperative pain and bruising[24]. In the long term, however, it is likely that the recurrence rate of surgery is higher than that of EVLA because of neovascularization, as is confirmed by the findings of the current analysis. One retrospective study suggested that RFA and EVLA were equally effective[25] and another that EVLA was superior[26]. Three small, short-term RCTs showed that RFA and surgery were about equally effective, but RFA-treated patients reported less postoperative pain and physical limitations, faster recovery, fewer adverse events, and superior HRQOL compared with patients who underwent surgical stripping [27-29].

An earlier RCT showed that liquid UGS was less effective than surgical stripping[30], but that study used liquid sclerosant, which is washed out relatively quickly and induces less vasospasm and sclerous formation than foam sclerosant[17]. Clinical trial registries indicate that several important RCTs of RFA vs.

Table 3: Comparisons of four different treatment options for lower extremity varicose veins

Comparisons	Unadjusted for follow-up			Adjusted for follow-up		
	Crude OR	95% CI	P	Adjusted OR	95% CI	P
UGFS vs strip	0.15	fi0.49 to 0.80	.64	0.12	fi0.61 to 0.85	.73
EVLA vs strip	1.54	1.02 to 2.07	<.0001	1.13	0.40 to 1.87	.006
RFA vs strip	0.87	0.29 to 1.45	.003	0.43	fi0.19 to 1.04	.16
EVLA vs UGFS	1.39	0.81 to 1.97	<.0001	1.02	0.28 to 1.75	.013
RFA vs UGFS	0.71	0.08 to 1.34	.03	0.31	fi0.29 to 0.91	.27
EVLA vs RFA	0.68	0.17 to 1.18	.009	0.71	0.15 to 1.27	.016

CI, ConÏdence intervals; *EVLA,* endovenous laser ablation; *OR*, odds ratio; *RFA,* radiofrequency ablation; *UGFS,* ultrasound guided foam sclerotherapy.

stripping and UGFS vs. surgery are currently ongoing[13]. In addition to anatomic success rates, patient-reported outcomes such as HRQOL, treatment satisfaction, symptom relief, and side effects are pivotal in a comparison between invasive and noninvasive therapies for venous insufficiency. Compared with surgery, EVLA-treated patients appreciated EVLA more than surgery because they reported fewer side effects and their HRQOL improved better and faster[22, 23]. Patient-reported outcomes are especially important when two therapies are equally effective. For example, this current meta-analysis suggests that the anatomic success rates of UGFS and surgery are comparable, but patients' opinions may differ between these therapies. Also, cost-effectiveness assessments are lacking and should be included in clinical trials. One study suggested that the RFA procedure was cost-saving from a societal perspective compared with surgery because the patient's physical function was restored faster and endovenous therapies can be performed in an outpatient setting, resulting in lower nonmedical costs[27]. Minor and relatively common postoperative complications of ligation and stripping are wound infection, hematoma, lymphorrhagia, and hypertrophic scarring. Other complications of surgery are nerve injury (7%) and deep vein thrombosis (<2%)[31-36]. Because the sclerosant enters the deep venous system, UGFS may be associated with several specific complications such as migraine, temporal brain ischaemia, and scotomas, especially among patients with a foramen ovale[37]. As in surgery, most patients will experience ecchymosis and pain (often described as "a pulling chord") for 1 to 2 weeks after endovenous therapies. Dysesthesia, phlebitis, and skin burns have been reported in a small proportion and deep vein thrombosis in <1% of patients after EVLA and RFA[38-41]. To our knowledge, this is the first meta-analysis and meta-regression analysis comparing different treatment options for lower extremity varicose veins, and the results suggest that there are significant differences between interventions. The detected differences are in accordance with the few available comparative studies suggesting a good face validity of our findings. More than 60 studies met our inclusion criteria. To increase homogeneity of the comparison, we restricted the analysis to studies that used US as primary end point. Because of the variation in follow-up duration, we adjusted the comparison between the therapies for this difference. Several sensitivity analyses were performed to assess the effects of study design, duration of follow-up, and sample size on our findings and they confirmed our initial results. Meta-analysis is associated with several limitations. A major limitation of this

analysis is that it included a heterogeneous mix of case series and RCTs. This rather unusual but methodologically and clinically sound approach was chosen because of the lack of comparative RCTs in phlebology, as was illustrated by the systematic review. To increase the quality of analysis, both the MOOSE and QUORUM guidelines were followed as much as possible[14, 15]. The objective of this study was to inform physicians about four therapies commonly used in the treatment of lower extremity varicose veins and compare their efficacy based on the available data. An aggregation or ecologic bias, which occurs because group rates may not resemble individual rates, is unavoidable. Because we were unable to precisely describe the heterogeneous study populations, different inclusion criteria may have affected our findings (e. g., case series of endovenous therapies may have included more primary, nontortuous, interfascial GSVs than UGFS and stripping, and RFA is limited to veins of ≤12 mm due to the catheter size). Although we restricted the analysis to studies that used US to increase comparability, the standardization of the different definitions of success, which was based on consensus, may have affected our results. To minimize the effect of publication bias, an extensive English and non-English literature search was performed, including registries of clinical trials. Small studies were not excluded to reduce publication bias because their impact was weighted and the proportion of total weight of these studies was limited. A subanalysis limited to studies with >60 patients showed findings similar to those presented, confirming that the effect of the smaller studies was not substantial. The EVLA studies with limited follow-up are likely to reflect the centers' initial experience (i. e., learning curve), and the relatively large proportion of these studies may explain the lower success rates after 3 months compared with later intervals. Several studies from the 1970s and 1980s were excluded because US examination was not an outcome measurement. To further increase homogeneity of the analysis, it was restricted to studies that used ligation and stripping because this is the gold standard of surgical care and restricted to foam in sclerotherapy because it is superior to liquid sclerosant[17]. Also, we did not differentiate between concentration of sclerosant, which varied from 1% to 3%. However, a recent RCT demonstrated that the concentration of sclerosant (1% vs. 3%) was not a significant predictor of outcome in UGFS[42]. Because 89% of the studies were case series, a thorough quality assessment was not performed, but subgroup analysis suggests that the results of retrospective and prospective studies were not substantially different.

Conclusions
The results of this meta-analysis support the increasing use of minimally invasive interventions in the treatment of lower extremity varicosities. In the absence of comparative RCTs, it appears that EVLA is more effective than surgery, UGFS, and RFA. However, large, long-term comparative RCTs that include patient-reported outcomes, cost-effectiveness analyses, and safety assessment are needed to achieve the highest level of evidence for these novel therapies.

Author Contributions
Conception and design: TN, LA, MN Analysis and interpretation: TN, LA Data collection: RB, TN, MK Writing the article: RB, TN, LA Critical revision of the article: MK, MN, LA Final approval of the article: RB, MK, MN, LA, TN Statistical analysis: LA Obtained funding: Not applicable Overall responsibility: TN.

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