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SPECIAL ARTICLE

3D and Smart Foam, new avenues to explore, to improve the safety and effectiveness of ultrasound guided foam sclerotherapy

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ABSTRACT

Ultrasound-guided foam sclerotherapy is the least invasive care method for the treatment of varicose veins of the lower limbs. It is the treatment that patients choose when they know it exists. This prospective analysis aimed to show that it would be possible to perform a safer and more efficient ultrasound-guided foam sclerotherapy with the development of some significant advancements. The use of a tomographic imaging device for easy access to 3D imaging brings considerable progress to ultrasound-guided foam sclerotherapy thanks to the reconstruction of the venous axis to be treated in its entirety and in volume. Significant is also the concept of introducing flexibility in the choice of sclerosing liquid/air ratios, Smart Foam, to complete the 1:4 ratio which has never been subject of any study.

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KEY WORDS: Venous insufficiency; Varicose veins; Sclerotherapy; Imaging, three-dimensional.

Putting the patient first means offering him the least invasive treatment as first-line treatment. Ultrasound-guided foam sclerotherapy (UGFS) is the least invasive care method for the outpatient treatment of varicose veins of the lower limbs. It puts the comfort and well-being of the patient at the center of attention.

The objective is to obliterate the incontinent saphenous axis, to eliminate reflux, injecting sclerosing foam, while respecting the maximum volume of 10 mL per session. The sclerosing foam pushes back the blood column and causes a spasm of the vein wall, known as "vasospasm," leading to the retraction and fibrosis of the pathological vein. It is a conservative method.

The injection must be performed with ultrasound guidance, whether with direct puncture (saphenous axis ø <8 mm)[1] or with a short catheter (saphenous axis ø >8 mm).[2]

Thanks to ultrasound guidance, it is possible to follow the path of the echogenic sclerosing foam during the injection and to interrupt it with accuracy at the level of the junctions with the deep venous system.

Today, two significant advancements, if developed, would make it possible to perform a safer and more universal ultrasound-guided foam sclerotherapy for the treatment of incompetent saphenous axes:

- progress in medical images, thanks to the use of a tomographic imaging device, installed on a latest-generation ultrasound system, allows easy access to 3D imaging which reconstructs the venous axis to be treated in its entirety and in volume;[3, 4]
- the concept to be explored of introducing flexibility in the sclerosing liquid/air ratios for the sclerosing foam making: new "Smart Foam" approach.

Progress in medical images

Methods

Advances in medical imaging have ensured the development and optimization of sclerotherapy. B mode ultrasound images have enabled a more universal and effective sclerotherapy.

In 1989, thanks to the use of ultrasound devices, sclerotherapy entered a new era. It has become ultrasound-guided sclerotherapy. Doppler ultrasound devices have made it possible to move from a care technique reserved for the less advanced stages of venous disease and for the treatment of reticular veins and telangiectasias, to a care technique also allowing the treatment of incontinent saphenous axes, regardless of their diameter, depth, position or composition.

However, B mode ultrasound images have their limits: even if conventional ultrasound has made, for about thirty years, considerable progress, it is somewhat schematic.[5]

In longitudinal section: the practitioner has only a partial and rectilinear view of the incontinent venous axis to be treated (Figure 1).[6]

In cross section: the practitioner only sees a superposition of trunks. The junctions are not revealed (Figure 2).

The new images in 3D, by offering a volumetric and complete view of the saphenous axes to be treated, facilitate and secure, the practice of sclerotherapy and reinforce its effectiveness.

An innovative vascular imaging system transforms any latest-generation ultrasound into a 3D imaging device.

A Bluetooth sensor is attached to the high-frequency

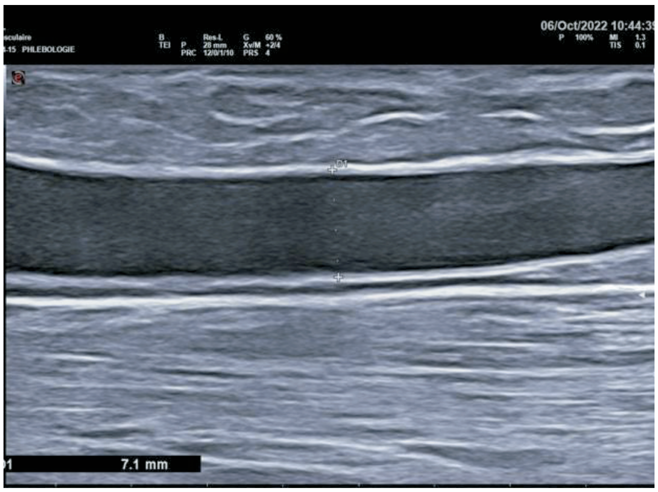

Figure 1.—B mode images in longitudinal section provide a partial and rectilinear vision of the incompetent axis to be treated.

Figure 3.—Bluetooth sensor installed on the probe to obtain 3D tomographic images.

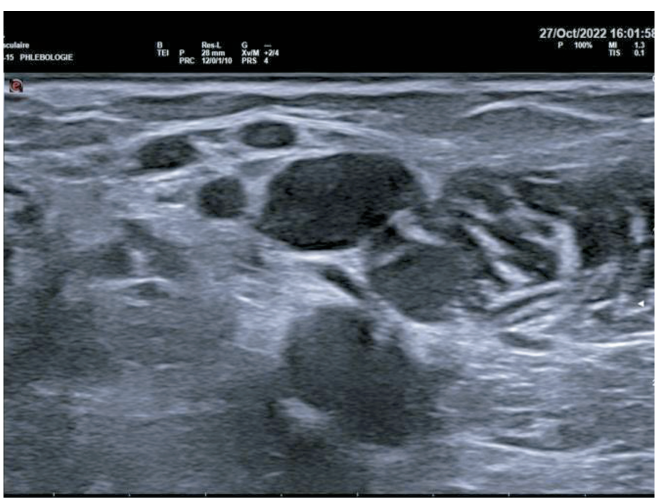

Figure 2.—B mode images in cross section provide only a superposition of trunks without revealing the junctions.

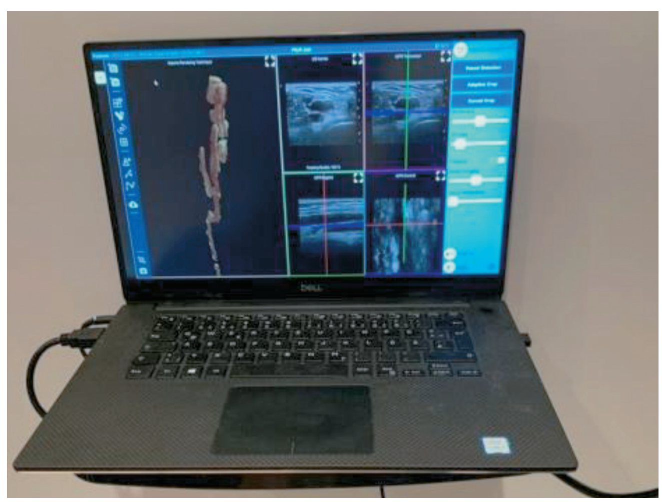

Figure 4.—Software to analyse and store images.

surface probe, between 10 and 18 MHz, allowing good visualization of the superficial venous system (Figure 3). This installation is completed by a video box connected to the ultrasound device. The images can then be analysed and stored with specific software installed on a conventional PC equipped with a high-performance graphics card (Figure 4).

The 3D mode provides MRI-like quality images (Figure 5).

Results

3D imaging brings considerable progress to ultrasound-guided foam sclerotherapy.

Safer ultrasound-guided foam sclerotherapy:

In a single scan of the probe, the 3D images make it possible to visualise the path of the saphenous axis and its tributaries (Figure 6). The practitioner can examine the

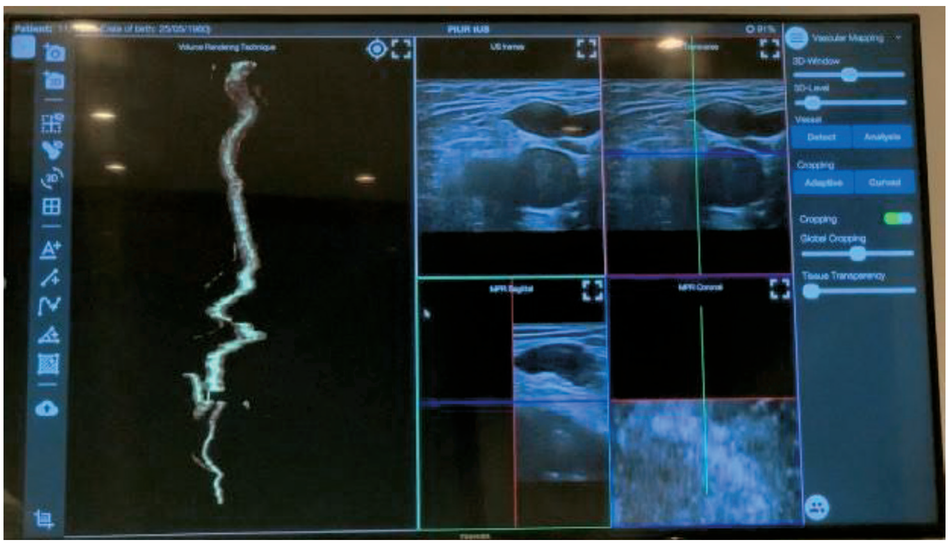

Figure 5.—3D venous mapping, in its entirety and in volume, is reconstructed from the B mode images thanks to tomography.

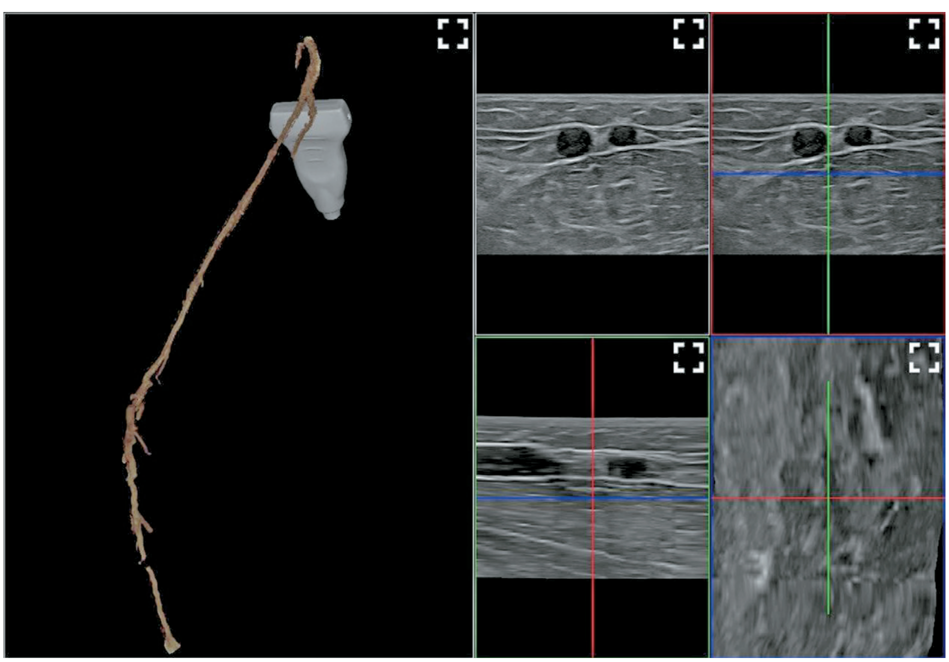

Figure 6.—Incompetent great saphenous vein prior to UGFS treatment.

venous axis to be treated in the 3 planes of space thanks to the rotation of the image. Depending on the orientation, the same axis appears tortuous or rectilinear (Figure 7).

3D imaging makes it possible, based on B-mode images, to discover the tortuosity of the incompetent venous axis to be treated (Figure 8). Only sclerosing foam can distribute itself in such ectasias to cause vasospasm leading to fibrosis.

3D mode provides better visualization of venous anatomical variants. One of the characteristics of the superficial venous system, at the level of the popliteal fossa, is to have inconstant saphenopopliteal junctions. A better visualization of these venous anatomical variants is provided by 3D imaging. In a single scan of the probe, the venous mapping is reconstructed in three dimensions, based on the B-mode images, highlighting the junctions with the deep venous system (Figure 9).

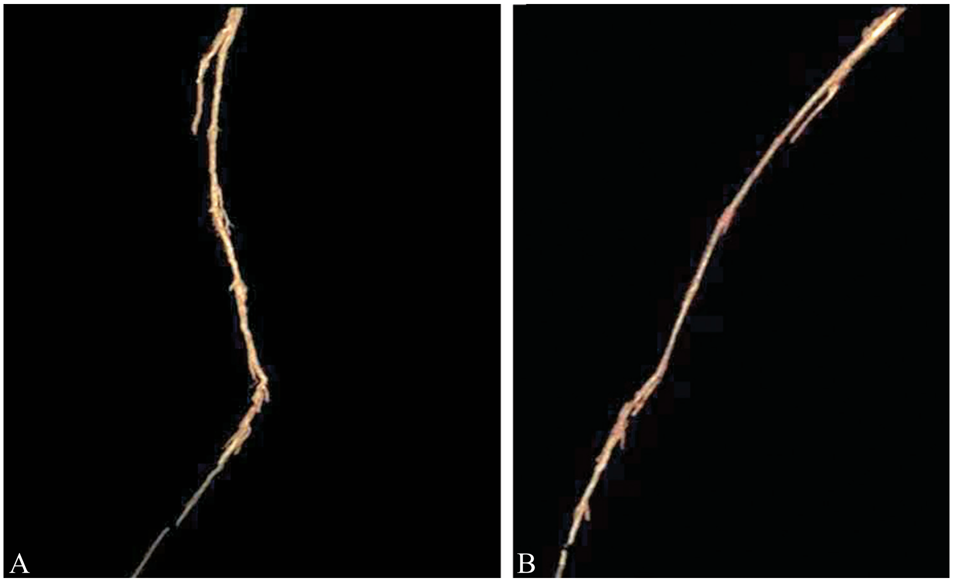

Figure 7.—A) The saphenous axis appears, on certain planes, tortuous; B) on other planes, the same saphenous axis appears more rectilinear, which shows the importance of rotation to benefit from a complete examination of the saphenous axis to be treated.

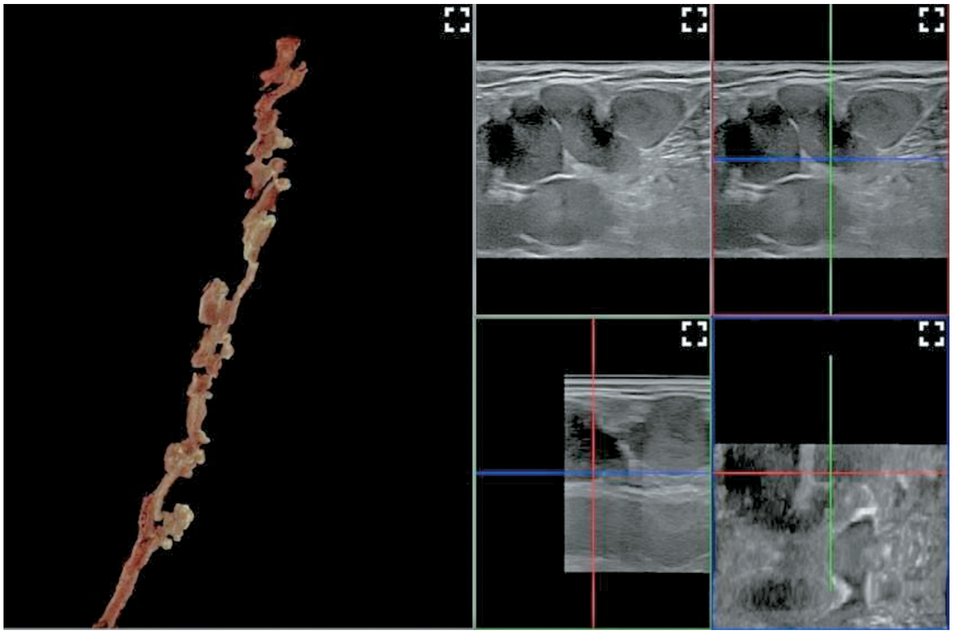

Figure 8.—Tortuosity of a post-surgical recurrence of GSV with cavernoma: on the left in 3D mode, on the right in B mode.

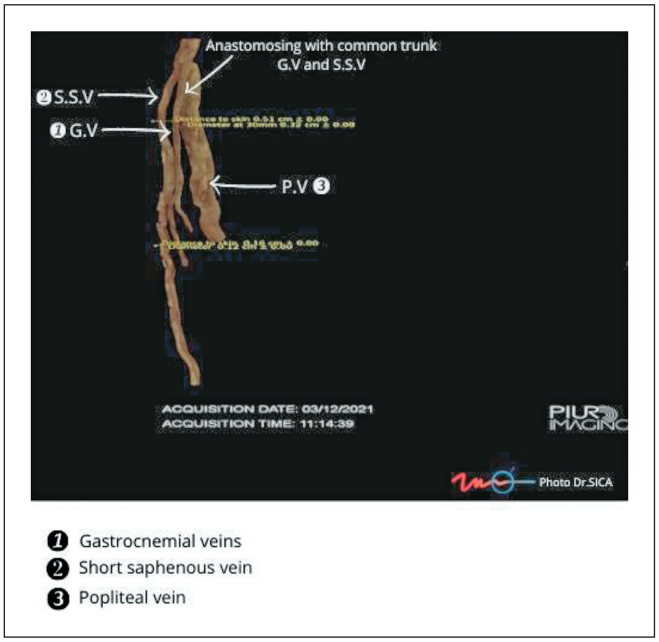

Figure 9.—Short saphenous vein presenting a common junction with the gastrocnemius veins in the popliteal vein.

More effective ultrasound-guided foam sclerotherapy

The 3D mode allows the identification of the tributaries which risk, by aspirating the sclerosing foam, compromising a sufficient vasospasm to achieve good fibrosis of the refluxing saphenous axis. The tributaries are only visible in cross section in B mode and disappeared very quickly. In 3D mode, the good visualisation of the tributaries allows, at the time of injection, when the foam reaches the level of the junction with the tributaries, to carry out a compression with the probe at this level to avoid the dispersion of the foam in the tributary (Figure 10, 11).

The practitioner can also choose the best access point to ensure an effective vasospasm (Figure 12).

The practitioner can control the effectiveness of the vasospasm and see the reduction in the diameter of the vein in its entirety (Figure 13, 14, 15).

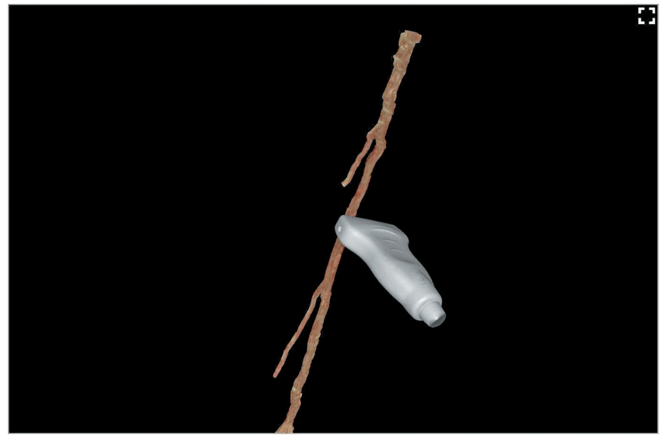

Figure 10.—Tributaries of a great saphenous vein (GSV) in 3D mode.

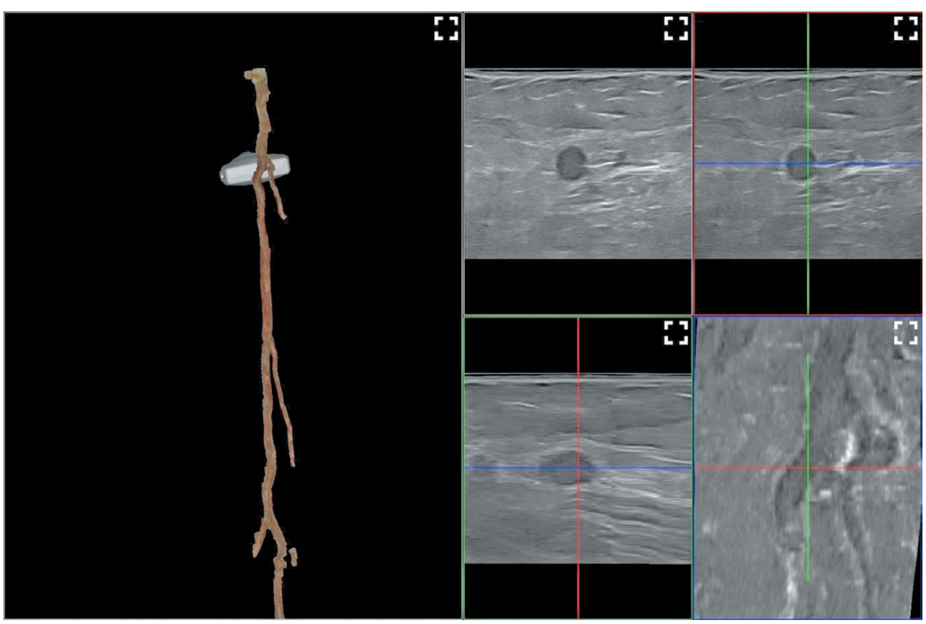

Figure 11.—Tributaries of a great saphenous vein (GSV) in 3D mode from a different perspective.

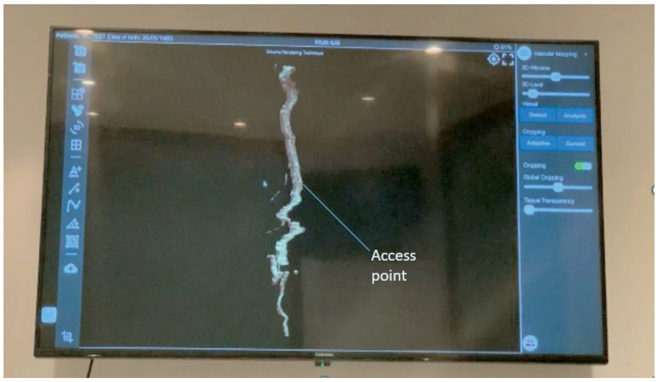

Figure 12.—Choice of the best access point for optimal diffusion of the foam and maximum effectiveness.

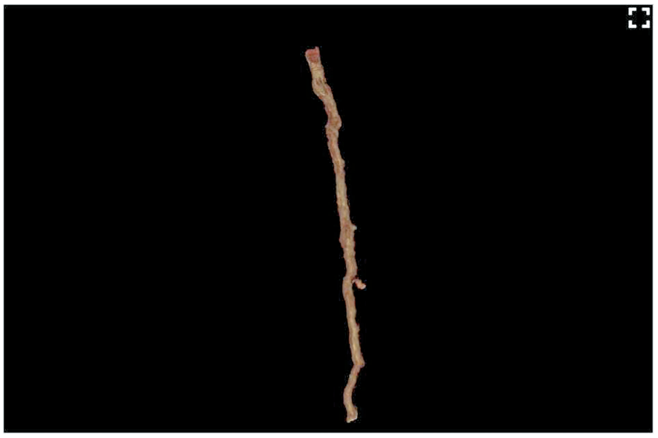

Figure 13.—Small saphenous vein (SSV) prior to UGFS treatment.

Complementary analysis options facilitate the practice of sclerotherapy at different levels. The digital calculation, at several levels, of the diameters of the vessels to be treated, helps to evaluate the theoretical quantity of sclerosing foam to be injected (Figure 16).

This quantity must not exceed 10 ml of foam per session, which is sufficient to sclerose the saphenous axes, including those of large diameter, thanks to the expansion ability of the sclerosing foam which fills the vessel and repels the blood column and thanks to the Marangoni effect.[7, 8]

The practitioner interrupts the injection when the vasospasm is sufficient and is predictive of good fibrosis and obliteration.

However, this theoretical volume means that the patient does not have to be re-punctured because it is sufficient to obliterate the incontinent saphenous axis with one injection.

The calculation of this theoretical volume is useful since it is difficult to immediately re-puncture the saphenous axis when foam is already present, due to the onset of vasospasm and the difficulty to visualize the venous axis because of the foam.

The calculation of the volume of the vessel is also useful, after the injection, for measuring the result obtained, on the whole of the saphenous axis treated, and determining the retraction and the fibrosis as a percentage of the initial volume.

Soon, digital mapping will render drawing vein mapping by hand obsolete.

Smart foam approach

Observations

The ratio (volume of sclerosing liquid on volumes of air) and the method of making the foam play a fundamental role in the texture of foam but have not yet been considered in studies.

The current protocol of a standard ratio 1:4 (1 volume of sclerosing liquid for 4 volumes of air) lacks clinical studies

The physical characteristics of the foam, the size of the bubbles, the varicose filling, the rheology (flowing) of the foaming embolism and the lifetime of the foam depend first on the sclerosing liquid/air ratio, secondly on the method of making the foam and thirdly on the concentration of the sclerosing liquid used (0.5%, 1%, 2%).

At present, only one study has been published which compares concentrations for the same texture, using a 1:4 ratio.[9] The field of ratio diversification, however promising, remains unexplored.

No study validates the choice of the standard ratio 1:4 and yet this ratio was introduced and fixed in the European recommendations for sclerotherapy in 2013 and for this reason, alone, it remains in force.

Certainly the 1:4 ratio has made it possible to develop the method, but it is also the reason for sometimes insufficient results, with large diameters saphenous veins,[10] and undoubtedly also responsible for avoidable side reactions:

- the number of treatment sessions needed to achieve a therapeutic result was on average 1.3 in the group using Polidocanol in foam form *versus* 1.6 in the control group using Polidocanol in liquid form. The higher the liquid dose, the more sessions are needed;
- foam has superiority over liquid in terms of risk reduction, due to the small amount of sclerosing liquid used in its manufacture;
- the arrival of anaphylactic shock, angioedema, urticaria, asthma, which is certainly rare, is also probably dependent on the dose of sclerosing liquid.

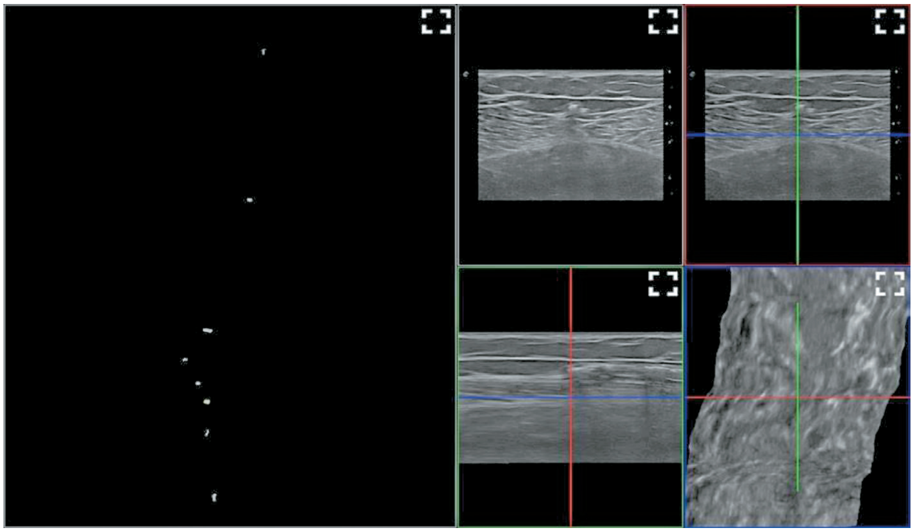

Figure 14.—The same SSV at the time of vasospasm.

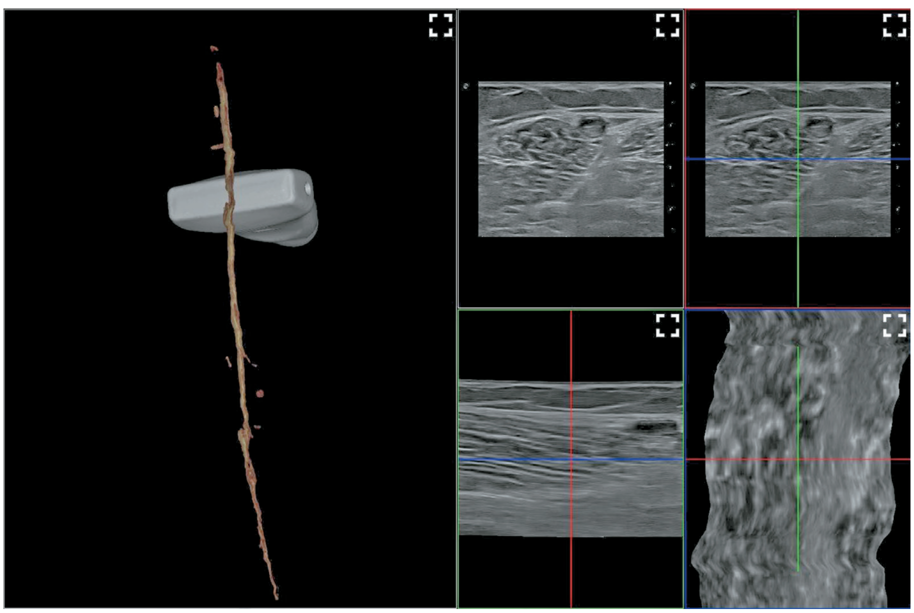

Figure 15.—Sclerosed small saphenous vein (SSV) in 3D.

These findings plead, a priori, in favor of ratios integrating a greater quantity of air for the treatment of large-diameter incompetent saphenous veins: 1:6 or even 1:8.

The method to make sclerosing foam plays a fundamental role in the texture of the foam too and in its possibility of standardization.

There are different mechanical methods to make sclerosing foam:

- transfer foaming. It is obtained with the 3-way device and with the double female connectors. The large and unknown number of manipulations, the double release of silicone (2 syringes) and the differences in the equipment used make it a type of foaming that is very material-operator dependent and therefore ill-suited for a standardization of foam making and for the introduction of new specialized ratios according to the vein size to be treated (Figure 17);
- thermodynamic foaming. It is obtained with the one-way device, the only one of this type. This foaming is characterised by instantaneous degassing and use of a

Figure 16.—Digital calculation of diameters in blue (in the online version).

Figure 17.—Different mechanical devices to make sclerosing foam by transfer foaming.

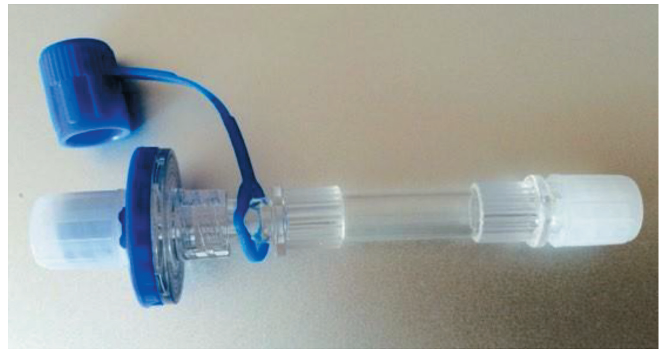

Figure 18.—One-way device to obtain thermodynamic foaming.

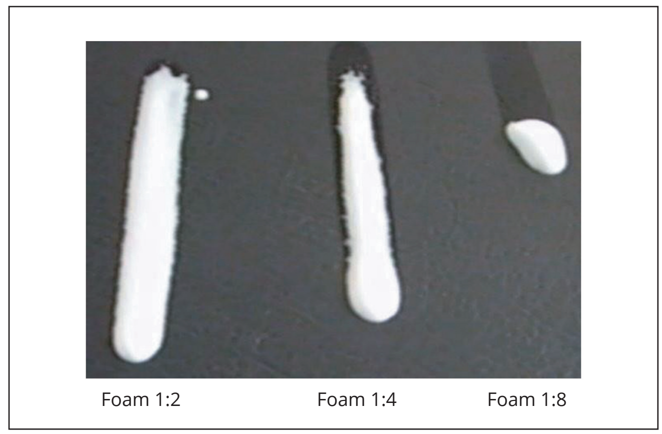

Figure 19.—Spreading after 20 seconds of sclerosing foams deposited at the same time at the top of an inclined plane.

single syringe, which halves the dose of silicone compared to the transfer foaming method, while silicone affects the stability of the foam. Moreover, with the one-way device, the foaming is less operator dependent and more homogeneous. This device is ideally used to ensure the stability of foam. It is suitable for the standardization of foam making and for the diversification of ratios (Figure 18).

Advantage of considering the rheology (flow) of the foam

Depending on the ratio adopted, it is possible to distinguish 3 main foam textures:

- wet and more flowing foams (ratio 1:1, 1:2 to 1:3), which are fluid and ideally diffuse into small vessels (reticular veins and telangiectasias), improving micro sclerosis;
- medium foams (ratio 1:4), which cannot move easily in small vessels and do not sufficiently fill saphenous veins of large diameters;
- dry and more expansive foams (ratio 1:5 to 1:8), which ideally and fully fill the largest diameters by moving slowly against the walls, achieving conditions for better contact with the endothelium and better ultrasound-guided foam sclerotherapy (Figure 19).

The concentration of the sclerosing liquid conveniently completes the texture of the foam:

- higher concentration of 1% or 2%, even very exceptionally 3%, for drier and dense foams, with a ratio of 1:5 to 1:8;
- concentration of 0.125%, 0.25% or 0.33%, for softer and more fluid foams, with a ratio of 1:1 to 1:3;
- concentration of 0.5% or 1% for medium foams with a ratio of 1:4.

Results

The protocol of the future, to be explored, is the notion of “Smart Foam.”

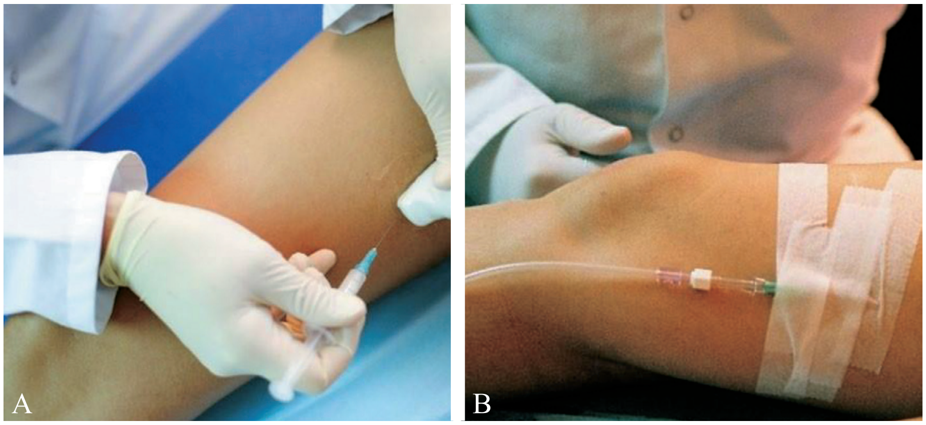

Figure 20.—A) Direct puncture – incompetent saphenous axes with a diameter <8 mm; B) short catheter – incompetent saphenous axes with a diameter >8 mm.

• Smart Foam for reduced side effects of sclerosing foam.

The ratios of 1:6 to 1:8 (1 volume of sclerosing liquid for 6 to 8 volumes of air) also have the advantage of being able to reduce the quantity of sclerosing liquid used for the treatment of large-diameter saphenous veins and to fibrose and obliterate them effectively, while respecting the upper limit of 10 mL of volume of foam per session.Finally, it is the way to reduce the side effects encountered, which are to be attributed more to the intrinsic quantity of sclerosing liquid contained in each syringe of sclerosing foam, than to the quantity of air injected.

• Smart Foam for greater efficiency of sclerosing foam.

It seems more and more accepted and adopted by a growing number of professionals who practice UGFS, that the modification of the ratios linked with the diameters of the axis to be treated, would be one of the solutions to improve the effectiveness of the results of UGSF, both for large varicose veins and very small vessels.

The ratios preferably used would be 1:1, 1:2, for diameters up to 3/4 mm, ratios of 1:3, 1:4, 1:5 for average diameters ranging from 4 to 8 mm and ratios of 1:6 to 1:8 for incontinent saphenous veins >8 mm.[11]

Conclusions

3D mode:

• provides a complete visualization, on the 3 planes of space of the venous anatomy of the patient;

• allows a better understanding of the venous path when it is tortuous (choice of the injection point) and when it is complex (presence of tributaries and anatomical variants in particular);

• simplifies the measurement and evaluation of the volume of foam to be injected (thanks to the digital calculation, at several levels, of the diameters of the vessels to be treated and thanks to the entire and volumetric view of the venous axis to be treated);

• facilitates control of the venous axis as a whole and on the 3 planes of space, post-sclerotherapy.

"Smart Foam" (SF) concept:

• makes it possible to use ratios other than the standard 1:4, which is not always appropriate, for a technique which has precisely the advantage over other techniques of being highly adaptable to the venous morphology of each patient;

• makes it possible to choose the best foam texture for optimal results choosing the more suitable device for the standardization of foam making and for the diversification of ratios adapting the sclerosing liquid/air ratio to the diameter of the venous axis to be treated;

• promotes the reduction of side effects that are sometimes encountered.

The combination of the 2 "3D+SF" advances would reinforce the safety, precision and effectiveness of ultrasound-guided foam sclerotherapy treatments and improve the practice of this non-invasive therapy, chosen by patients, when they know it, because comfortable and without any immobilization (Figure 20).

Moreover, it is inexpensive and easily accessible to all, even if specific practical training is necessary for obtaining safe and good results.

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Conflicts of interest.—Mario Sica is the President and founder of the International School of Sclerotherapy (Ecole Internationale de Sclérothérapie, EIS). The EIS is a partner of *Esaote*® and *Sterivein*®. Mario Sica is a vascular advisor for *Piur Imaging*®. Alain Monfreux is a honorary member of the French Society of Phlebology and Honorary President of "Club Mousse". Alain Monfreux is a lecturer at the International School of Sclerotherapy and was the designer of the one-way device *Sterivein*® to produce sclerosing foam.

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