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2nd European Consensus Meeting on Foam Sclerotherapy 2006
Tegernsee, Germany

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Rationale

The spread of Foam Sclerotherapy has resulted in the renaissance of sclerotherapy as a treatment method for varicosis [11]. The correct use of sclerosant foam for the right indications for various forms of varicosis has now become established world-wide as safe and effective. The joint recommendations drawn up by European experts in this field at the 1st European Consensus Meeting on Foam Sclerotherapy (1st ECMFS) in 2003 [6, 7] were possibly able to contribute to this. A second meeting (2nd ECMFS), prompted by new findings and continuous further development of the method, but also because it had not been possible to consider all the relevant aspects of Foam Sclerotherapy in depth at the first meeting, was held by an expanded European expert committee in April 2006, in Tegernsee.

Objective

The broad spectrum of individual procedures used in Foam Sclerotherapy described in the literature can make it difficult to integrate this treatment option into daily practice managing varicosis, particularly for relatively inexperienced colleagues. The results of the 1st ECMFS helped to introduce a certain systematic approach to diagnosis and treatment. However, there is always a need to review and update these results at set intervals in order to consider scientific advances and to include important issues when developing the method. Thus, updated recommendations compiled by colleagues with many years' experience can usually be adopted unanimously after in-depth discussion. These are then useful for quickly becoming more familiar with this form of treatment. Illustrative descriptions of the various results, which were endorsed by more than half the participants enable colleagues to compare their own methods with those of the majority of experts. The presentation of the recommendations neither makes any claim to completeness, nor is it intended to restrict by any means the doctors' liberty to treat as they see fit. The recommendations are merely and exclusively a presentation of the contents that were systematically compiled during the preparations for the 2nd ECMFS and were considered adequate by the participants and subsequent working groups. Thus they take into account the currently available personal experience, opinions and scientific knowledge of the meeting participants with regard to the corresponding questions and problems.

Methodology

The 29 experts in the field of Foam Sclerotherapy from 11 nations (Table I and Fig. 1) were sent their first questionnaire in January 2006. They were

Table I: Participants

BENIGNI Jean-Patrick, France; BIHARI Imre, Hungary; BREU Franz Xaver, Germany; CABRERA Antonio, Spain; CAVEZZI Attilio, Italy; COLERIDGE-SMITH Phillip D, United Kingdom; DIAMAND Jean-Marc, France; FRULLINI Alessandro, Italy; GUEX Jean-Jérôme, France; GUGGENBICHLER Stefan, Germany; HAMEL-DESNOS Claudine, France; JAVIEN Arkadiusz, Poland; KAHLE Birgit, Germany; KERN Phillipe[1], Switzerland; MARSHALL Markward[2], Germany; MILLERET René, France; MORRISON Nick, USA; PANNIER Felicitas, Germany; PARTSCH Bernhard, Austria; PARTSCH Hugo, Austria; RABE Eberhard, Germany; RAMELET Albert-Adrian, France; RYBAK Zbigniev, Poland; SCHADECK Michel, France; STREJCEK Jaroslav, Czech; STÜCKER Markus[1], Germany; TESSARI Lorenzo, Italy; WILDENHUES Bernward, Germany; WOLLMANN Jan-Christoph, Germany

[1] participants who could not attend the final Consensus Meeting but contributed through questionnaire
[2] participants who did not submit questionnaire but attended the final Consensus Meeting

Figure 1: Participants

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requested to freely give their views and experience with respect to the recommendations of the 1st ECMFS 2003, to urge discussions on topics that had received little if any attention to date, and to suggest any recommendations that should be changed or included for the first time.

Evaluation of this first questionnaire led to the preparation of a second, considerably more extensive 29-page questionnaire which enquired about personal preferences in the medically relevant aspects of Foam Sclerotherapy. The questions referred to a number of different topics (Table II). The questionnaire contained a total of 38 open questions which could be answered individually, and 83 closed questions which the participants were able to mark with their choice from a selection of different possible answers.

Completed questionnaires from 28 experts were evaluable. The results were entered in a database table for further processing. As a rule, answers to "please tick" questions were shown purely descriptively in tables or graphs. The answers to open questions were grouped together according to their content and – assuming they agreed with each other – summarised.

Beginning in March 2006, the organisers prepared the provisional versions of the statements on the basis of the processed data. "Consensus" statements were prepared providing that all, or almost all, of the participants had given the same or at least very similar answers to the questions. In the case of "only" absolute or simple majorities, less obviously concurring responses, or a low number of answers, "Descriptions" of the responses were prepared.

The answers to all the questions and the accompanying "Consensus" or "Descriptions" statements were presented to the participants during the meeting itself in April 2006. All the topic complexes were discussed in-depth, and all participants were able to adopt, modify or even reject any of the "Consensuses" and "Descriptions". New aspects that arose for the first time during the discussions were considered immediately. In addition, two working groups were given the task of conducting the concluding assessment of the items "The Role of (Duplex-) Ultrasound in Foam Sclerotherapy" and "Efficacy Evaluation of Foam Sclerotherapy". Following the discussions at the 2nd ECMFS these spent several weeks working on the final wording of the individual recommendations and presented their final results in March and April 2007 to be voted on. Since then, the organisers and the participants at the 2nd ECMFS have taken the opportunity several times to present some aspects of the results.

Table II: Topics of the 2nd ECMFS

General questions (personal experience, treated indications, number of patients treated)
Access material
Access location
Sclerosant foam preparation
Concentrations
Foam volumes
Efficacy evaluation of Foam Sclerotherapy
Safety aspects of Foam Sclerotherapy
Contraindications
Compression after Foam Sclerotherapy
Patient information
Endovenous catheter techniques
Duplex ultrasound in Foam Sclerotherapy
Miscellaneous
All topics comprised 3 to 20 questions each, usually categorized by the different indications

Results

1. General Questions

The first group of questions asked about each participant's personal experience with Foam Sclerotherapy, the indications treated with sclerosant foam, and the number of patients treated with sclerosant foam so far.

1.1. Indications for Foam Sclerotherapy

The survey revealed that the indications for Foam Sclerotherapy include treatment of Great Saphenous Veins (GSV), Small Saphenous Veins (SSV), Tributaries (Trib), Recurrent Varicose Veins (RecVV), Perforating Veins (PerfV), Reticular Veins (RetV), Telangiectasia (Tel), Venous Vascular Malformations (VVM) and other indications like haemorrhoids, Baker's cysts and vulvar varices. RecVV are treated most frequently by most of the participants, followed by large-calibre veins (SSV, Trib, and GSV) (Fig. 2). Small-calibre varicose veins (Tel) are treated less frequently with sclerosant foam. Other indications (haemorrhoids, Baker's cysts or vulvar varices) are treated only by a few participants and/or much less often.

1.2. Experts' experience

Most of the participants had significantly more than 5 years' experience using sclerosant foam for all indications except Tel, VVM, haemorrhoids, Baker's cysts or vulvar varices. For these indications, experience was stated only by few experts and most commonly with less than 5 years' duration. Trib and RetV were the indications most of the participants had the longest experience with using sclerosant foam.

1.3. Number of treated patients

Answers to the question about the number of patients treated with

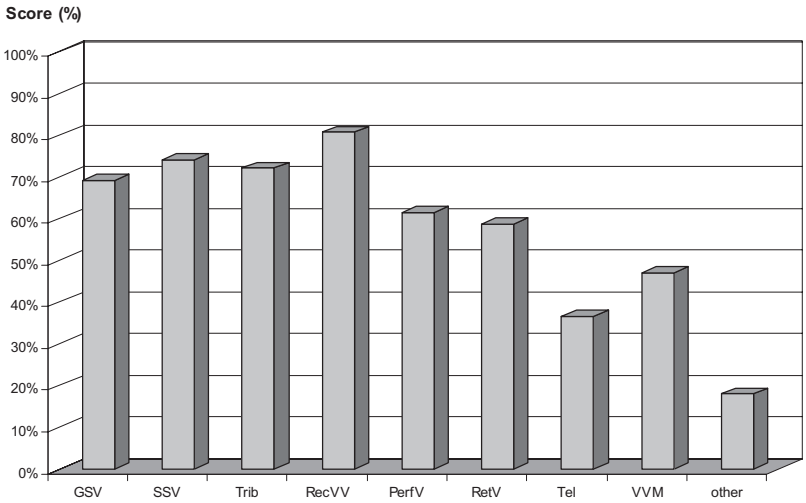

Figure 2: Use of Foam Sclerotherapy
Answers to the question "How often do you treat ... (indication) with Foam Sclerotherapy?" could be given choosing from "never" (0%), "seldom" (1–33%), "sometimes" (34–66%), "often" (67–99%), or "always" (100%); A score of 100% means that the indication is "always" treated by "all" participants – a score of 0% means that the indication is "never" treated by all participants

Foam Sclerotherapy for the different indications showed great variability: For any indication, there was at least one participant who had not treated this indication so far, whereas others had very high numbers of treated patients (Table III). The analysis showed that until early 2006, almost 184 000 patients had been treated with Foam Sclerotherapy by the invited experts, and that most of the patients had received sclerosant foam for treatment of Trib, followed by RetV and GSV. VVM were treated with sclerosant foam in 327 patients. The median values probably express best what is treated frequently or infrequently.

2. Access Material

The target vein can be accessed and sclerosant foam can be injected using various means of access material and techniques [13, 34, 40, 54, 56]. The group of questions about the preferred access material was intended to identify what is most frequently used by the participants for a specific indication, and what is considered most effective, easy to use and/or safe. The answers showed that the participants use a variety of different materials, including common injection needles, either as "direct puncture" technique [26] (puncture of the target vein with needle attached to the syringe) or "open needle" technique [8] (puncture of the target vein with bare needle only – syringe not yet connected to needle), butterfly needles, short catheters (short plastic tube for endovenous placement with removable needle for puncture) or long endovenous catheters (placement using Seldinger's technique).

Description 1: Access material for Foam Sclerotherapy; see Table IV

Table III: Number of treated patients

	sum	mean	median	range
GSV	28 870	1110	265	(0–5000)
SSV	14 821	570	150	(0–5540)
Trib	38 350	1475	750	(0–6000)
PerfV	16 285	626	200	(0–5000)
RecVV	19 645	756	300	(0–3000)
RetV	35 065	1349	450	(0–6000)
Tel	28 045	1079	125	(0–10 000)
VVM	327	13	10	(0–50)
other	2502	96	0	(0–1500)

sum: cumulated number of patients treated by all participants
mean: mean number of patients treated by all participants
median: median number of patients treated by all participants
range: range of number of patients treated by all participants

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Table IV: Access material for Foam Sclerotherapy

	direct puncture	open needle	butterfly	short catheter	long catheter
GSV	++	+	+	+	+
SSV	++	+	+	+	+
Trib	++	+	+	+	
PerfV	++	+	+	+	
RecVV	++	+	+	+	+
RetV	++		(+)		
Tel	++		(+)		
VVM	++	+	+	+	

++ indicates what most of the experts use to access the target vein
+ indicates what is accepted by the experts, but is used less frequently than ++
(+) indicates what some of the experts use to access the target vein

The most frequently used access material for all treated indications is the common injection needle used for the "direct puncture" technique. For a skilled therapist, this is possibly the fastest and easiest option. Undoubtedly it is the cheapest possibility, but good hand-eye co-ordination is required if the "direct puncture" technique is used under ultrasound guidance [26, 40]. All other access materials are used less frequently, although there can be some theoretical advantages in using these techniques: after correct intravascular placement of a butterfly needle or a short or long catheter, sclerosant foam can be prepared as needed and can be injected without loosing any additional time for (re-)identifying or (re-)adjusting the target vein. The longer the time interval between foam preparation and injection, the more the foam quality could be affected [63].

Another question tried to specify lengths and diameters of the access material used in the different indications. Table V shows the most frequently given answers (mean values) for lengths and diameters of the needles used.

Description 2: Access material (needles); see Table V

Table V: Access material (needles)

	needle lengths (cm) low – high	needle diameter (mm) low – high (Gauge)
GSV	3.0–4.0	0.8 (21G)
SSV	3.0–4.0	0.6–0.8 (21–23G)
Trib	1.6–2.5	0.5–0.6 (23–25G)
PerfV	2.5–3.5	0.6–0.7 (22–23G)
RecVV	3.0	0.6–0.7 (22–23G)
RetV	1.6	0.4–0.5 (25–27G)
Tel	1.3–1.6	0.3–0.4 (27–30G)
VVM	3.0–4.0	0.6 (23G)

If a "short catheter" is used, the one most frequently used has a length of 4.5 cm and a diameter of 0.9 mm to 1.3 mm (17G–20G). If a butterfly is used, the tube length is 10 to 30 cm, and the needle has a diameter of 0.8 mm (21G), except for Telangiectasia, where a 0.4 mm needle diameter (27G) is used more often.

3. Access Location

The target vein can be accessed and sclerosant foam can be injected at various locations [13]. In Conventional Liquid Sclerotherapy, the point of venepuncture is typically identical to the point of intravenous drug release, and consequently to the area of highest pharmacological action of the sclerosant solution within the vein. In Foam Sclerotherapy, the point of vein access and the area of sclerosant action are not necessarily identical, since foam (depending on the physical-chemical properties of the foam, patient position, mode of injection and foam volume) can also act at a certain distance from the site of injection. If endovenous catheters are used, the point of venepuncture and intravenous drug release are typically not identical.

During the 1st ECMFS in 2003, it was recommended to puncture the vein (GSV or SSV) "at the safest and the most easily accessible location" at a distance from the sapheno-femoral junction of "at least 10 cm" [6, 7]. Therefore, when treating the GSV the vein was punctured at a very distal location on the thigh in some cases. If low volumes of sclerosant foam

were injected, the region immediately below the sapheno-femoral junction could not always reliably be filled with sclerosant foam. In the light of the experience of the participants at the 2nd ECMFS, the recommendation was revised to the effect that, with direct punctures, the vein be accessed and the injection be given at the proximal thigh to ensure that an adequate sclerosant foam effect is achieved in the region distal to the sapheno-femoral junction, even when using a volume of foam that can be considered safe (see Consensus 9 – Consensus 11).

Consensus 1: Access location for GSV treatment

When treating the GSV with direct puncture, it is recommended to access the vein at the proximal thigh. If long catheters are used, it is recommended to access the GSV below the knee.

Irrespective of the final access location in GSV-treatment, 55% of the participants try to release the foam intravascularly at the proximal thigh and 36% in the area of the groin (the latter in particular if long catheters are used and/or the sapheno-femoral junction is blocked, e.g. by external manual compression).

Consensus 2: Access location for SSV treatment

When treating the SSV with direct puncture, it is recommended to access the vein in the proximal or middle part of the calf.

86% of the participants do not access the vein directly in the popliteal fossa, but in the proximal or middle part of the calf. If the SSV is accessed in the popliteal fossa, special care should be taken to avoid inadvertent puncture of any concomitant artery. Trib or RetVV may be punctured at a location easily accessible (i.e. clearly visible or palpable, i.e. located superficially) or at a location close to the origin of its reflux. As for the treatment of GSV, the two locations are not interchangeable, since – with respect to maximum foam volumes per injection – an adequate amount of a sufficiently active sclerosant foam may not be able to reach the tributaries' origin if the access to the target vein is located too far distally. The discussion ended with the suggestion of a majority of participants to access the target vein (Trib or RetVV), at least for the primary injection, as proximally as possible.

Description 3: Access location for treatment of Tributaries and Recurrent Varicose Veins

When treating Tributaries and Recurrent Varicose Veins, it is recommended for a beginner to access the target vein at its proximal part.

Sclerotherapy of PerfV is particularly important in the treatment of poorly-healing crural ulcers and eliminating pathological recirculation. Individual reports about sclerosing PerfV have shown that adequate obliteration of these PerfV, and thus more rapid healing of ulceration, is possible with sclerosant foam [16, 27, 41, 47, 51, 52, 57]. However, due to the anatomical relationship to the deep venous system and the veins of the muscles, treatment must be given with utmost caution, and care taken not to exceed the maximum foam volume (see Consensus 9 – Consensus 11). Accompanying arteries and nerve branches are frequently intimately related to the PerfV [49]. Therefore, ultrasound guidance for puncture and injection is considered particularly important (see Consensus 26). Further, the majority of clinicians recommend not injecting the sclerosant foam directly into the PerfV, but into the neighbouring (dependant) varicosis.

Consensus 3: Access location for treatment of Perforating Veins

When treating Perforating Veins, it is recommended not to inject directly into the target vein.

4. Sclerosant Foam Preparation

Following the results of the 1st ECMFS, where sclerosant foam was defined and the main variables characterising sclerosant foam were identified [6, 7], at the 2nd ECMFS, much emphasis was put on the methods of foam preparation and the variables that can be controlled by the sclerotherapist, i.e. the type of gas, the relation of liquid and gas, and the concentration of the tensio-active sclerosant agent, each of the latter with respect to the indication.

4.1 Methods of sclerosant foam preparation

A group of questions dealt exclusively with the methods of foam preparation depending on the indications to be treated. Table VI shows initial results of the questionnaire. Interestingly, only a few experts use Monfreux foams[1], and if so, only for C_1-varicose veins, whereas almost all of the participants use compact and viscous foams, i.e. Tessari-Foam[2] or Tessari/DSS-Foam[3] for any indication,

1 Monfreux's foam is generated using a glass syringe containing liquid sclerosant. The outlet of the syringe is sealed by a plastic cap. Pulling back the piston generates a subatmospheric pressure, drawing air into the syringe through the gap between the syringe body and the piston.

2 Tessari foam is generated with two disposable plastic syringes. One syringe contains liquid sclerosant, the other contains gas. The outlets of the syringes (preferably Luer-Lock) are connected with a three-way tap at a 90° angle. The content of both syringes is pumped backward and forward approximately 20 times. The turbulent flow generates foam.

3 Tessari/DSS (Double Syringe System) Foam, based on the basic method by Tessari, is generated with two disposable silicone- and latex-free 10 ml plastic syringes (one with a rubber plunger). One syringe contains 1 part of liquid sclerosant, the other contains 4 parts of gas. The outlets of the syringes (preferably Luer-Lock) are connected with a two-

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Table VI: Methods of sclerosant foam preparation

	Monfreux	Tessari	Tessari/DSS+	Other++
GSV	0%	44%	52%	4%
SSV	0%	44%	52%	4%
Trib	0%	43%	50%	7%
RecVV	0%	46%	50%	4%
PerfV	0%	41%	52%	7%
RetV	2%	43%	48%	7%
Tel	13%	43%	35%	10%
VVM	0%	50%	44%	6%

\+ Tessari/DSS includes EasyFoam
++ "Other methods" of foam preparation are (unpublished or undisclosed) personal techniques

especially for large-calibre varices, as has been recommended previously [6, 7].

Consensus 4: Methods of sclerosant foam preparation

For preparation of sclerosant foam, the method of Tessari and the Tessari/Double-Syringe System (DSS) are recommended for all indications.

4.2 Gases for sclerosant foam preparation

Gases which are used for foam preparation should be physiologically tolerated at therapeutic doses.[4] Most of the experts have had good and wide experience using air as the gas component. Air predominantly consists of nitrogen and oxygen. Carbon dioxide and other gases are contained in smaller amounts. Besides air, a few experts also use O_2 or CO_2 or mixtures of both. Table VII shows the gases that are currently used by the experts for foam preparation.

Table VII: Foam preparation – used gas fraction

	air	gas+
GSV	87%	13%
SSV	88%	12%
Trib	88%	12%
RecVV	87%	13%
PerfV	88%	12%
RetV	92%	8%
Tel	90%	10%
VVM	83%	17%

\+ CO_2–O_2 mixtures in various compositions or pure CO_2 was used by a few experts

Consensus 5: Gas used to prepare sclerosant foam

For the production of sclerosant foam, air is accepted / proposed as the gas component for foam preparation for all indications. A mixture of CO_2 and O_2 can be used, too.

4.3 Relation of liquid and gas

The volume relation of liquid and gas directly influences the stability and viscosity of a sclerosant foam [62]. It was recommended in 2003 that the larger the diameter of the vein to be treated, the more viscous the sclerosant foam should be, in order to obtain better results [6, 7]. Also in 2003, liquid-plus-gas ratios of 1 plus 3 up to 1 plus 4 were recommended for the Tessari technique, and 1 plus 4 for the Tessari/DSS technique.
Three years later, most of the experts have chosen the "1 plus 4" ratio for all indications (Table VIII), and the following consensus was found:

Consensus 6: Ratio of liquid and gas for sclerosant foam preparation

The preferred ratio of liquid and gas for preparing sclerosant foam for all indications is 1 + 4 (1 part liquid + 4 parts gas). For Reticulars and Telangiectasia, ratios of liquid and gas from 1 + 1 up to 1 + 5 (1 part liquid + 1 to 5 parts gas) are used; the majority use 1 + 4.

4.4 Drug

For sclerosant foam preparation, the experts usually use Polidocanol[5] or Sodium Tetradecyl Sulphate, depending on personal experience, preferences and/or availability in the respective country. No differences were found between users of Polidocanol or Sodium Tetradecyl Sulphate

way connector at a 180° angle. The content of both syringes is pumped backward and forward 5 times (generating additional pressure by firmly holding one syringe's plunger) and again 7 times (without additional pressure).

4 A "therapeutic dose" of Sclerosant Foam in accordance with the consensuses of the 2nd ECMFS is up to 10 ml of foam (prepared with air in a ratio of 1 plus 4). This foam volume comprises 8 ml of air. In this volume, approximately 1.7 ml of gaseous oxygen and 6.2 ml of gaseous nitrogen are contained. After intravenous injection, O_2 is dissolved in a relatively low volume of blood, and nitrogen is dissolved in approximately 2.2 l of blood, i.e. in approximately 50% of the normal blood volume of a 60 kg adult [28].

5 also "Lauromacrogol 400".

Table VIII: Liquid plus air ratios used

	1 plus 1	1 plus 2	1 plus 3	1 plus 4	1 plus 5
GSV	0%	4%	19%	78%	0%
SSV	0%	4%	19%	78%	0%
Trib	4%	0%	19%	74%	4%
RecVV	0%	4%	19%	78%	0%
PerfV	4%	0%	15%	81%	0%
RetV	8%	4%	19%	62%	8%
Tel	11%	11%	16%	53%	11%
VVM	0%	0%	5%	95%	0%

concerning the methods of foam preparation or the liquid-to-gas ratios used. Possible differences in the efficacy and safety, or differences in the physico-chemical properties of foams made from Polidocanol or from Sodium Tetradecyl Sulphate were not addressed during the meeting.

4.5 Miscellaneous

Another parameter which, besides the preparation method, sclerosant, type of gas and liquid-gas ratios, considerably affects the quality of the foam, is the material used, i.e. above all the adapters and the syringes [62]. Hence, many of the questions referred to personal preferences with regard to the materials used during preparation of the foam. As expected, the answers included a large number of different suggestions about the types, makes, materials and sizes of syringes, and different types of adapter. Features such as silicone-free syringes, good slideability of the piston during the injection, and generally standardised preparation are seen as important. A number of respondents recommended the material proposed for the Tessari/DSS technique [64]. Material specifications in connection with a clearer definition of the preparation method, the gas used, and the liquid-gas ratio can thus further improve foam standardisation, a subject that has gained in importance in recent times [9, 18, 36]. The majority of experts have seen the need for standardised foam preparation (Fig. 3). Standardisation of foam preparation is seen to be more important for study purposes, possibly due to individual, many years' experience with the respective techniques used to prepare the foam which can then be considered as more or less "standardised".

5. Concentrations

Although there is evidence that sclerosant foam is more effective than the corresponding liquid sclerosant [25],

Consensus 7: Standardisation of sclerosant foam preparation

There is a need to standardise the preparation of sclerosant foam (for trials, not for daily practice).

at the 1st ECMFS no consensus was found concerning adequate concentrations of a liquid sclerosant to be transformed into a sclerosant foam for injection into a target vein. Therefore, this time much emphasis was put on figuring out the preferred concentrations of liquid sclerosants used to prepare the foam with simul-

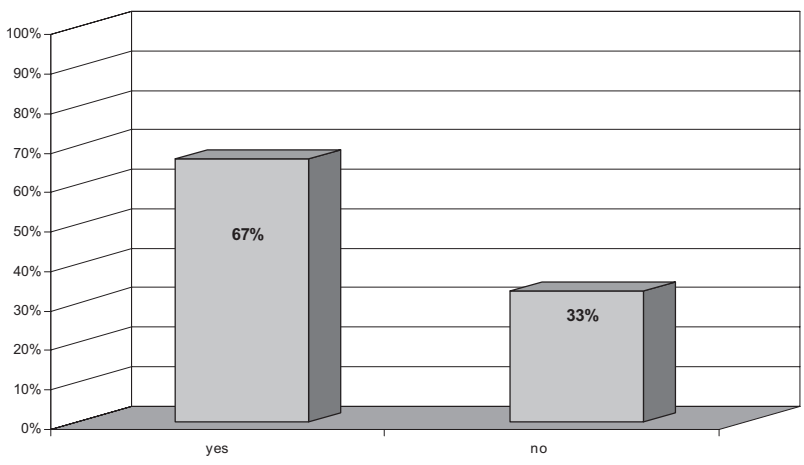

Figure 3: Necessity of foam standardization
Number of participants in percent answering the question "Is there a need to standardize foam production?" with "yes" or "no"

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taneous consideration of 1. indications and 2. vein diameters. Some experimental data comparing the properties of foams made from different concentrations exist [45, 62], but reliable clinical data allowing the selection of applicable concentrations are still scarce [12, 23, 24]. Consequently, the recommendations relating to adequate concentrations are based on the pooled experts' personal experiences and are separated into consensuses or descriptions for Polidocanol and descriptions for Sodium Tetradecyl Sulphate.

5.1 Concentrations of Polidocanol

The answers to the question, which concentration of Polidocanol should be chosen to produce foam for which indication, produced 7 consensus statements and 1 description (for treatment of VVM, which is regularly treated by only a few experts). For a better understanding and overview, the statements are summarised in one single table (Table IX).

Consensus 8: Concentrations of Polidocanol / Indication; see Table IX

A similar question showed that the diameter of the vein is a more important criterion than the indication when selecting the Polidocanol concentration. Although this led to some overlapping with the previous question, Table X gives a more accurate selection of suitable Polidocanol concentrations if several concentrations are considered adequate for a particular indication (Table IX).

Description 4: Concentrations of Polidocanol / Diameter; see Table X

Since the experts consider that both the efficacy and the tolerability of the foam depend on the concentration and the volume injected, all the figures for the concentration must be seen in connection with the figures for the injection volumes.

5.2 Concentrations of Sodium Tetradecyl Sulphate

As for Polidocanol, the questions about the choice of adequate concentrations of liquid sclerosant were also asked about Sodium Tetradecyl Sulphate. The answers of the experts with experience in using this agent are summarised in Table XI (concerning indications) and Table XII (concerning diameters of the veins).

Description 5: Concentrations of STS / Indication; see Table XI

Description 6: Concentrations of STS / Diameter, see Table XII

6. Foam Volumes

In Foam Sclerotherapy, the injected foam volume influences at least two relevant aspects, i.e. an efficacy aspect and a safety aspect. The 1st ECMFS recommended, predominantly for safety reasons, to limit the total volume of foam injected during one treatment session to not more than 6–8 ml of sclerosant foam. In 2003, there was no consent about any recommended foam volume per puncture (i.e. per single injection) for indications other than C_1-varicose veins ("not more than 0.5 ml per injection"). Since then, experience among the participants has grown, and published data showed good results for different moderate injection volumes in C_2-varicose veins [21, 22, 23, 29, 34, 44, 60]. The 2nd ECMFS questionnaire asked about foam volumes per injection, per leg and per

Table IX: Concentrations of Polidocanol / Indication

	liquid	0,25%	0,5%	1%	2%	3%	4%
GSV				+	++	++	
SSV				+	++	+	
Trib				++			
RecVV			(+)	++	++	+	
PerfV			(+)	++	+	(+)	
RetV	(+)	(+)	++	+			
Tel	++*	(+)*	(+)*				
VVM			+	++	+		

Note: Concentrations given refer to liquid Polidocanol to be transformed into a sclerosant foam
++ indicates what most of the experts use to prepare foam for this indication
+ indicates what is also used by the experts, but less frequently than ++
(+) indicates what is used by some or a few of the experts or seldom
++* For sclerotherapy of Tel with Polidocanol, it is recommended to use liquid sclerosant agents at first
(+)* If foam is used, it is recommended to use small amounts of foam of 0.25%, possibly of 0.5%

Table X: Concentrations of Polidocanol / Diameter

	liquid	0,25%	0,5%	1%	2%	3%	4%
< 1 mm (Tel)	++*	(+)*					
1–3 mm (RetV)	(+)	+	++	(+)			
3–4 mm		(+)	++	++			
5–6 mm			+	++	+		
7–8 mm				+	++	++	
9–10 mm				(+)	+	++	
> 10 mm					+	++	(+)

Note: Concentrations given refer to liquid Polidocanol to be transformed into a sclerosant foam
++ indicates what most of the experts use to prepare foam for veins with this diameter
+ indicates what is also used by the experts, but less frequently than ++
(+) indicates what is used by some or a few of the experts or seldom
++* For treatment of veins of < 1 mm diameter (Tel) with Polidocanol, Foam Sclerotherapy is not recommended as a treatment of first choice
(+)* If Foam Sclerotherapy is done with Polidocanol, the preferred concentration is 0,25%

Table XI: Concentrations of STS / Indication

	liquid	0,2%	0,5%	1%	2%	3%
GSV			(+)	+	+	++
SSV			(+)	++	+	+
Trib	(+)		+	++	(+)	
RecVV			+	++	++	++
PerfV			+	++	++	(+)
RetV	++*	++*	+*	+*		
Tel	++**	+**				

Note: Concentrations given refer to liquid Sodium Tetradecyl Sulphate to be transformed into a sclerosant foam.
The information in Table XI is based on the experience of 6 of the experts
++ indicates what most of the experts use to prepare foam for this indication
+ indicates what is also used by the experts, but less frequently than ++
(+) indicates what is used by some or a few of the experts or seldom
* Foam Sclerotherapy of RetV with Sodium Tetradecyl Sulphate is not recommended by a majority. If Foam Sclerotherapy is done with STS, the preferred concentration is 0.2%. 0.5% and 1% are used less frequently
** Foam Sclerotherapy of Tel with Sodium Tetradecyl Sulphate is not recommended. If Foam Sclerotherapy is done with STS, the concentration is 0.2%

Table XII: Concentrations of STS / Diameter

	liquid	0,2%	0,5%	1%	2%	3%
< 1 mm (Tel)	++*	++*				
1–3 mm (RetV)	++**	++**	+**	+**		
3–4 mm	+	++	+	++		
5–6 mm		+	++	+	(+)	+
7–8 mm			++	++	+	++
9–10 mm				+	+	++
> 10 mm				+	+	++

Note: Concentrations given refer to liquid Sodium Tetradecyl Sulphate to be transformed into a sclerosant foam.
The information in Table XI is based on the experience of 6 of the experts.
++ indicates what most of the experts use to prepare foam for veins with this diameter
+ indicates what is also used by the experts, but less frequently than ++
(+) indicates what is used by some/a few of the experts or seldom
* Foam Sclerotherapy of Tel with Sodium Tetradecyl Sulphate is not recommended. If Foam Sclerotherapy is done with STS, the concentration is 0.2%
** For treatment of veins of 1–3 mm diameter (RetV) with STS, Foam Sclerotherapy is not recommended by a majority. If Foam Sclerotherapy is done with STS, the preferred concentration is 0.2%. 0.5% and 1% are used less frequently

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session, again in consideration of efficacy and safety. The questionnaire also differentiated between "average volumes" (so to speak for "normal" cases) and "maximum volumes".
For the treatment of GSV, the answers to the questionnaire ranged from less than 2 ml to up to 10 ml of sclerosant foam per injection, a range similar to the survey results of the 1st ECMFS [6, 7]. The variety is mainly due to the different methods of accessing the vein (with the "direct puncture" technique, the smallest amounts, with endoluminal catheters, the largest amounts of foam are injected), and to the site of foam release into the vein. Figure 4 and Figure 5 show the results for the average and the maximum foam volume for GSV treatment. The resulting consensus is part of Table XIII, where the consensuses for all indications are summarised and categorised into "average" and "maximum" volumes per injection. No expert exceeds a sclerosant foam volume of 10 ml per injection into the GSV, and more than two thirds of the experts inject not more than 4 ml per puncture on average. For conditions other than "average", e.g. for larger diameters, the experts inject slightly more than average (Fig. 5). Two thirds (65%) do not inject more than 6 ml, even at maximum per puncture. The volumes injected by the experts using endoluminal catheter techniques are better represented in Consensus 10 or Consensus 11, since usually they inject the whole foam volume at once, i.e. the foam volume per injection is identical to the foam volume per leg or per session.
Most of the experts did not see a necessity to calculate the foam volume before injection. The few who saw a necessity recommended

– calculating the volume following the equation [diameter (mm) × 3,14 / 5 = volume of sclerosant foam (in ml)]

or adjusting the volume to

– less than 4 ml of sclerosant foam for varicose veins of less than 6 mm and more than 4 ml of sclerosant foam for varicose veins of more than 6 mm diameter;

or

– less than 5 ml of sclerosant foam for varicose veins of less than 9 mm and more than 5 ml of sclerosant foam for varicose veins of more than 9 mm diameter.

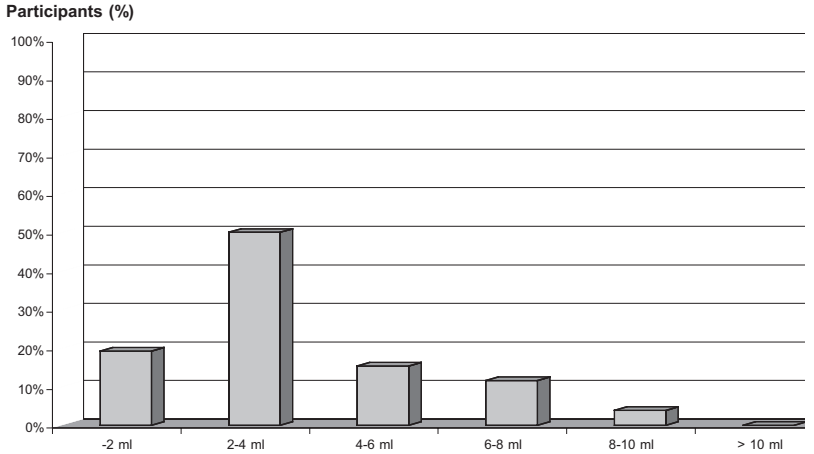

Figure 4: *Average* foam volumes for GSV *per puncture*
Number of participants in percent injecting the indicated *average* foam volumes *per puncture* for treatment of GSV

Consensus 9 (see Table XIII) shows the summary of average and maximum foam volumes per puncture. In several indications, multiple injections of small volumes of foam are possible. Then, the single injection volumes accumulate, so that finally the recommendations of Consensus 10 or Consensus 11 apply.

Consensus 9: Foam volumes per puncture; see Table XIII

At the 1st ECMFS, the maximum recommended volumes for C_2-varicose veins per session were 6 to 8 ml for Tessari and Tessari/DSS foams, but only 4 ml for Monfreux foams [6, 7]. Three years later, the experts recommend slightly increased maximum foam volumes per leg and per session (Consensus 10, Consensus 11). Besides more experience, one reason for an increased maximum volume is that "liquid" or "large-bubbled foams" (e.g. Monfreux foams) are no longer recommended for injection into any type of vein whatsoever, but only Tessari- and DSS-foams (Consensus 4).

Consensus 10: *Maximum* foam volume *per leg*

The recommended *maximum* volume of sclerosant foam *per leg* (injected in one or more injections) is 10 ml.

Especially if more than one indication is treated in one leg, the maximum volume of sclerosant foam per leg should not exceed 10 ml. If in one leg the injected volume of sclerosant foam has already reached the recommended maximum volume of scle-

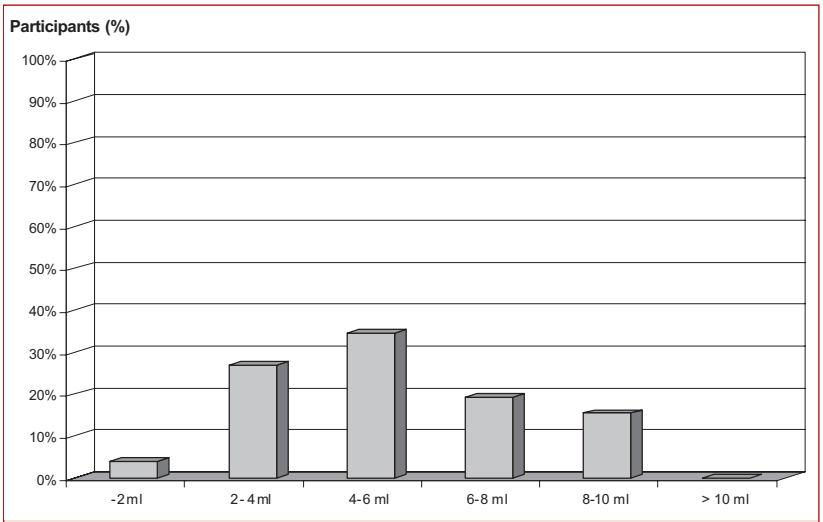

Figure 5: *Maximum* foam volumes for GSV *per puncture*
Number of participants in percent injecting the indicated *maximum* foam volumes *per puncture* for treatment of GSV

per session, depending on the vein calibres. Two-thirds of the experts limit the volume of foam when treating only C_1-varicose veins to not more than 6 ml, whereas 87% limit the volumes to less than 10 ml per session, if only C_2-varicose veins are treated (Fig. 6).

One reason for this could be that in a large survey on Sclerotherapy [21], transient side effects appeared to be more frequent if C_1-varicose veins had been treated with foam. Although the reason for this is not clear, limitation of the maximum volume in C_1-varicose veins seems justified.

A couple of final questions in the group "foam volumes" tried to scrutinise the experts' attitudes towards Foam Sclerotherapy, especially to-

Table XIII: Foam volumes per puncture

	Average volume of sclerosant foam per puncture	Maximum volume of sclerosant foam per puncture	Remarks
GSV	2 to 4 ml	up to 6 ml	
SSV	2 to 4 ml	up to 4 ml	
Trib	up to 4 ml	up to 6 ml	some use up to 10 ml at maximum
RecVV	up to 4 ml	up to 8 ml	
PerfV	up to 2 ml	up to 4 ml	not directly into Perforating Vein
RetV	< 0,5 ml	< 1 ml	
Tel	< 0.5 ml	< 0.5 ml	
VVM	2 to 6 ml	< 8 ml	

rosant foam per session (10 ml, Consensus 11), any other indication on the same or on the other leg should not be treated at the same session.

Consensus 11: *Maximum* foam volume *per session*

The recommended *maximum* volume of sclerosant foam *per session* (injected into one or both legs) is 10 ml.

It must be emphasised again that the foam volumes injected on average per session usually remain below the maximum values, i.e. between 2 and 8 ml (Description 7).

Description 7: Average foam volume per session

The recommended average volume of sclerosant foam *per session* (injected into one or both legs) is 2 to 8 ml.

It may be of some interest that different maximum volumes are injected

Description 8: Maximum foam volumes per session for C_1- and C_2-varicose veins

The recommended maximum volume of sclerosant foam for C_2-varicose veins per session (injected into one or both legs) is 10 ml. If only C_1-varicose veins are treated, some limit the maximum volume of sclerosant foam to 4 ml per session.

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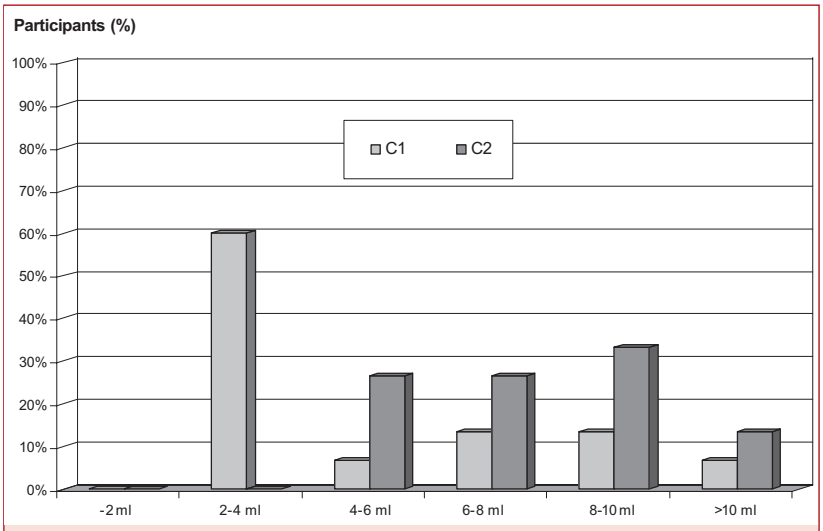

Figure 6: Different maximum foam volumes per session in C_1- and C_2-varicose veins
Number of participants in percent injecting the indicated *maximum* foam volumes *per session* for treatment of C_1-varicose veins. In contrast, the number of participants in percent injecting the indicated *maximum* foam volumes *per session* for treatment of C_2-varicose veins

wards the connection between injection volumes, concentrations and/or foam quality. The discussion resulted in 2 descriptions (Description 9, Description 10) and one consensus (Consensus 12).

Description 9: Limitation of volume or concentration during Foam Sclerotherapy

There might be a tendency rather to limit the volume than to limit the concentration during Foam Sclerotherapy.

Description 10: Limitation of foam volume per session

It is recommended to limit the volume of foam per session, even if the patient requires more than one treatment.

Consensus 12: Foam quality for treatment of large veins

If treating large veins, foams should be used that are as compact/viscous as possible.

7. Efficacy of Foam Sclerotherapy

7.1 Immediate signs after Foam Sclerotherapy

One question tried to evaluate the role of possible immediate changes of the vein shortly after injection. Frequently but not always, with ultrasound imaging, a yasospasm can be detected shortly following injection of sclerosant foam. Published literature provides data about the frequency of vasospasm after foam injection and about the positive predictive value of vasospasm concerning *short-term* treatment success [25]. In another multicenter randomized clinical trial, the decision to re-inject sclerosant foam in the same session was based on the onset of vasospasm after the preceding injection, in order to minimize the total foam volume [24]. For a slight majority of the participants, the occurrence of a vasospasm of the injected vein is an indicator for the "immediate" efficacy of foam injection.

Description 11: Indication of *initial* efficacy by the occurrence of vasospasm

For a slight majority of participants, the occurrence of vasospasm of the injected vein is an indicator for the *initial* efficacy of foam injection.

Some participants mentioned that the appearance of vasospasm could indicate that the injected foam (volume and concentration) is sufficient. On the other hand, several experts also have made the experience that a vein could re-open despite the occurrence of vasospasm (and despite "immediate" or "short-term" success). Therefore, the majority of participants felt that the occurrence of vasospasm of the injected vein was *not* an indicator for a (finally) sufficient foam volume or for a sufficient foam concentration, and the following two descriptions were also released:

Description 12: Indication of a sufficient foam volume or concentration by the occurrence of vasospasm

For the majority of participants, the occurrence of vasospasm of the injected vein is *not* an indicator for a sufficient foam volume or for a sufficient foam concentration.

Consequently, since vasospasm may only show that the vein has been *affected* by the foam, whether or not volume and concentration have been sufficient to ensure a finally successful outcome, no recommendations

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Description 13: Choice of injection volume determined by the occurrence of vasospasm

For the majority of participants, the injected volume of sclerosant foam should *not* be chosen by the occurrence of vasospasm.

have been adopted about possible procedures after *non*-occurrence of a spastic vessel reaction. Some of the experts would perform a re-injection at the same session:

Description 14: Procedures after non-occurrence of vasospasm

If no vasospasm occurs during or shortly after Foam Sclerotherapy, the majority do not recommend re-injecting any foam at the same session or to repeat the injection. Some re-inject with the *same or lower volume* of sclerosant foam of the *same* concentration, some of a *higher* concentration.

7.2 Evaluation of the therapeutic effects of Foam Sclerotherapy

One topic of the meeting of utmost importance was the dialogue about how to assess the therapeutic outcome of Foam Sclerotherapy, i.e. the efficacy of treatment. Especially the roles of clinical evaluation and of duplex ultra-ultrasound were intensively discussed. Since the topic was so complex, not all aspects could be dealt with during the 2nd ECMFS, and finally a working group was set up. They completed their work (concerning duplex ultra-ultrasound) after several proposals, ongoing discussions and multiple changes in March/April 2007.

The easiest way of assessing the therapeutic effects of Foam Sclerotherapy is by clinical evaluation and advances in patients' symptoms. Duplex ultra-ultrasound is not used for evaluation in every indication:

Consensus 13: Evaluation of the therapeutic effects of Foam Sclerotherapy

The therapeutic effects of Foam Sclerotherapy in a patient's limb should be evaluated clinically and according to symptoms. The effects of Foam Sclerotherapy in GSV, SSV, Tributaries, Recurrent Varicose Veins, Perforating Veins and Venous Vascular Malformations should also be evaluated by duplex-ultrasound.

Irrespective of the modality of clinical and technical assessment of any therapeutic effect, the optimum timeframe for this assessment should be adhered to. Consensuses were found for suitable timeframes for immediate, short-term, mid-term and long-term efficacy evaluation.

Consensus 14: Evaluation of short-term therapeutic effects

Immediate results of Foam Sclerotherapy on GSV, SSV, Tributaries, Recurrent Varicose Veins, Perforators, Reticular Veins and Venous Vascular Malformations should be evaluated after up to one week. The short-term therapeutic effects of Foam Sclerotherapy on the patients' limb overall should be evaluated after 4–12 weeks and on Telangiectasia 3–4 weeks after the end of treatment.

Consensus 15: Evaluation of mid- and long-term therapeutic effects

The mid-term therapeutic effects of Foam Sclerotherapy on the patients` limb overall, on GSV, SSV, Tributaries, Recurrent Varicose Veins, Perforating Veins, Reticular Veins, Telangiectasia and Venous Vascular Malformations, should be evaluated after 2 years, long-term results after (at least) 5 years.

After clinical evaluation, duplex ultrasound evaluation (see chapter 13) should be performed to control efficacy in certain indications. If at the first follow-up visit no signs of efficacy are found clinically and/or using ultrasound (see Consensus 28), the treatment is usually repeated, but some changes (foam volumes and sclerosant concentrations) are made for this re-treatment, if applicable.

Description 15: Procedures after unsuccessful treatment at the first follow-up visit

If no signs of successful treatment have occurred at the first follow-up visit, the majority repeat the treatment with the *same or a lower volume* of sclerosant foam of a *higher* concentration. (Some repeat the treatment with higher volumes *and* a higher concentration).

8. Safety Aspects of Foam Sclerotherapy

To increase the safety of Foam Sclerotherapy during the procedure itself, various suggestions have been published [5, 14, 22, 29, 40], or were submitted by the experts prior to the 2nd ECMFS. They included suggestions concerning body and leg position, ultrasound guidance of the injection and post-injection control, suggestions concerning the quality of foam and additional recommendations. The role of sclerosant foam (quality, concentration and injection volumes) as a relevant aspect concerning the safety of the procedure has already been addressed in previous topics. In this chapter, all the remaining recommendations are summarised either as descriptions or as consensuses, separated by indications.

8.1 Safety aspects of Foam Sclerotherapy in GSV and SSV

It must be emphasised that most of the other experts also use limited volumes per puncture and per session

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Description 16: Increasing safety during GSV treatment with Foam Sclerotherapy

To increase safety during treatment of GSV, a slight majority use limited volumes per puncture and per session, *and* – for injection with needles and short catheters – keep to a minimum distance of 8 to 10 cm from junctions.

(see Consensus 9), but tend to inject the foam a little bit closer to junctions. Especially if long catheters are used, release of the foam into the vein is typically at a distance of 2–5 cm from the junctions, but in this procedure the junctions are usually blocked, e.g. by external manual compression [60, 61], and the leg is elevated.

The recommendations to increase safety during treatment of GSV or SSV with foam are summarised in Consensus 16. They aim at keeping "fresh foam" as long as possible in the area of desired activity, and at avoiding the onset of side effects caused by the distribution of active foam into regions not intended to be treated. Injection of very viscous foam is thought to stay longer in the vein segment to be treated. Immediate compression of the injected vein segment, early movement of the patient's leg or a Valsalva manoeuvre could cause fresh foam to be directed into regions where no treatment is intended. Ultra-sonographic assessment of foam distribution is an appropriate measure to trace the foam and therefore enables a decision to be made – e.g. by ankle dorsiflexion – whether the foam should be washed out of the vessels, if seen in the deep venous system. Besides the recommendations of Consensus 16, the recommendations concerning foam volumes and access location should be kept in mind.

Consensus 16: Increasing safety during GSV or SSV treatment with Foam Sclerotherapy

To increase safety, the following is recommended during treatment of GSV or SSV with Foam Sclerotherapy:

- Avoidance of immediate compression over injected areas
- Ultra-sonographic control of foam distribution
- Injection of very viscous foam
- No movement of the patient and leg for 2–5 minutes, no Valsalva manoeuvre and no muscle activation
- If foam[6] is detected in the deep venous system, muscle activation such as ankle dorsiflexion should be performed.

Frequently, small echogenic structures (bubbles) are seen in the deep venous system after injection of sclerosant foam. It is believed that, after a short time, foam bubbles turn into gas bubbles without an active sclerosant coating, i.e. without a sclerosing effect. Routinely performed muscle activation to wash away these bubbles is maybe not necessary if small amounts are seen in the deep venous system. If large amounts of these substances are seen in the deep venous system, muscle activation has been recommended to clear the vessels of any substances with possible sclerosing properties [14].

8.2 Safety aspects of Foam Sclerotherapy in Reticular Veins

For the treatment of RetV, avoidance of immediate compression and of early patient movement were recommended, too, and additionally the use of extremely small amounts of foam made of low concentrations of sclerosing agents.

6 foam as a bolus (i.e. in an excessive amount).

Consensus 17: Increasing safety during Reticular Vein treatment with Foam Sclerotherapy

For Reticular Veins, additional recommendations were to use extremely small amounts of foam of low concentration.

8.3 Safety aspects of Foam Sclerotherapy in Telangiectasia

Sclerosant foam is used more and more for the treatment of Tel. Preliminary experience [3, 48] and more recent studies [30], but also fears of possible side effects, made it necessary to re-discuss the use of sclerosant foam for this indication again at the 2nd ECMFS. Published data suggest a higher efficacy of Foam Sclerotherapy, but also a higher frequency of side effects [3, 30, 48]. Transient neurological episodes seem to occur more often if sclerosant foam is used instead of liquid [21]. Therefore, the following consensus was issued during the meeting (Consensus 18).

Consensus 18: Increasing safety during Telangiectasia treatment with Foam Sclerotherapy

To increase safety during treatment of Telangiectasia with Foam Sclerotherapy, it is recommended to use liquid sclerosant agents at first and to switch to small amounts of foam of low concentrations only if the effect is not sufficient. It is also recommended to limit the pressure on the syringe's plunger during injection.

8.4 Safety aspects of Foam Sclerotherapy in Venous Vascular Malformations

Inadvertent injection of sclerosing agents into an arterial part of Vascular Malformations (VM) could result in excessive tissue damage and necrosis, especially if sclerosant foam is injected. Therefore, a precise and accu-

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rate pre-sclerotherapeutic assessment of VM is of great importance, mainly to verify or exclude the existence of any arterio-venous shunts. Only "low flow" (i.e. purely Venous Malformations) should be treated, and – as in GSV treatment – very viscous sclerosant foams should be injected under ultra-sonographic control. Immediate compression over injected areas should be avoided, but later on compression with bandages should be applied.

Consensus 19: Increasing safety during Vascular Venous Malformation treatment with Foam Sclerotherapy

To increase safety during treatment of Venous Vascular Malformations with Foam Sclerotherapy, the same as for GSV *and* the use of compression bandages is recommended. Only purely *Venous* Vascular Malformations should be treated.

8.5 Body position in Foam Sclerotherapy

At the 1st ECMFS, the discussion about the "optimal body position" for Foam Sclerotherapy yielded several different opinions. Concerning efficacy, it was stated that leg elevation is helpful to increase the efficacy of sclerotherapy in general, because the diameter of the treated vein is reduced and hence the efficacy of sclerosing agents is increased. It was also stated that leg elevation could be helpful in closing incompetent tributaries, since foam would ascend to more distal parts of the vein. Concerning safety, it was discussed that leg elevation could prevent the foam from entering the deep venous system. Finally, at the 1st ECMFS, elevation of the leg was recommended by the majority of the participants for treatment of larger veins. At the 2nd ECMFS, leg elevation was discussed again, mainly from a safety perspective, and a majority said – having in mind the (relatively low) maximum foam volumes per injection – that leg elevation is not mandatory.

Description 17: Leg elevation during and/or after Foam Sclerotherapy

A majority think that leg elevation during Foam Sclerotherapy is not mandatory for safety reasons.

It must be emphasised that "not mandatory" is not equivalent to "not useful". With respect to efficacy, leg elevation is suitable to reduce the vein diameter, and this is commonly believed to allow the usage of smaller foam volumes or of lower concentrations to reach equal levels of efficacy. On the other hand, with regard to safety, leg elevation may delay – but not prevent – dislocation of foam or foam remnants into unwanted regions (i. e. into the proximal deep venous system), and this could prevent active foam from entering veins not intended to be treated. If small amounts of foam are used, possible dislocation of foam might not be an issue, and consequently, leg elevation is not mandatory from a safety point of view.

During the 1st ECMFS, no consensus was reached concerning the position of the upper body (elevated or not elevated). At the 2nd ECMFS, the topic was addressed again, and a slight majority felt that the upper body position is not relevant in Foam Sclerotherapy.

Description 18: Upper body position during Foam Sclerotherapy

A slight majority think that the position of the upper body during Foam Sclerotherapy is not relevant.

8.6 Compression of junctions in Foam Sclerotherapy

The advantages and disadvantages of compression of the junctions during Foam Sclerotherapy were extensively debated. The idea behind compression of junctions is to avoid immediate release of (larger mounts of) fresh foam into the proximal deep venous system or into the systemic circulation, and / or to extend the residence time of foam in the desired treatment area. "Compression" in this context can be performed either by external manual compression, by pressing down the duplex probe [60, 61], or by endoluminal blocking of the vessels by means of inflating a balloon [10, 20]. The majority of participants did not encounter problems if they did not compress junctions during foam delivery into large veins using direct puncture or open needle techniques. It was even stated that compression of junctions could be the reason for problems, since foam or foam remnants could be released as a bolus all of a sudden into the deep venous system or into the systemic circulation if the compression was released suddenly. A published case report was mentioned in this context [18], where it remains unclear what the reason for the onset of neurological problems was [9, 36, 42]. The experts using endoluminal catheter techniques on the other hand stated the usefulness of compression of the junctions, since endoluminal foam release is close to the junctions – with perhaps an increased "natural" risk of injecting the foam into the proximal deep venous system. During endoluminal treatment with the junctions blocked by external compression and the leg in an elevated position, no foam bolus has been detected entering the deep venous system upon release of the compression.

It must be emphasised again that the experts think that compression of junctions is not necessary provided

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Description 19: Compression of junctions during Foam Sclerotherapy

A majority think that compression of junctions in Foam Sclerotherapy is not necessary.

that the recommended foam volumes and the recommended sites of injection are adhered to. For the use of catheters, where the junctions are sometimes blocked by internal or external measures, there is limited experience and no comparative scientific data, although it is believed that blocking the junctions during catheter-delivered Foam Sclerotherapy helps to prevent foam from directly entering the proximal deep venous system, at least from directly entering via the blocked communication.

8.7 Additional safety measures in Foam Sclerotherapy

To increase safety during the procedure it was also mentioned that repeated active flexion-extension of the feet helps to clear the deep veins from foam which may have entered during the injection or thereafter. Some of the experts routinely make the patients perform such movements after injection, intending to eliminate the slightest risk that active foam could reach the deep venous system. The majority though do not recommend *routinely* performing repeated dorsiflexion of the feet.

Description 20: Repeated dorsiflexion of the foot after Foam Sclerotherapy

The majority of participants do not think that it is useful or necessary to *routinely* perform (repeated) dorsiflexion of the foot.

9. Contraindications

Both Sclerotherapy and Foam Sclerotherapy are very safe procedures, and the risk of complications has been demonstrated to be extremely low [15, 21, 43]. It is obvious that the known contraindications for Conventional Liquid Sclerotherapy (e.g., allergy to the sclerosant or acute superficial or deep-vein thrombosis) are also applicable for Foam Sclerotherapy. At the 1st ECMFS, possible *additional* contraindications (in addition to the contraindications known for Conventional Liquid Sclerotherapy) were discussed, especially "patent foramen ovale" (PFO) and "migraine".

9.1 Patent Foramen Ovale and Migraine

About 15–25% of the general population has a PFO [17, 58]. In most cases, the diagnosis "PFO" is not associated with other medical conditions. On the other hand, carriers of a PFO may encounter (paradoxical embolic) ischaemic attacks and are more likely to suffer from migraine with aura (i.e. with visual disturbances, paraesthesia etc) [58]. The 1st ECMFS recommended treating patients with known *symptomatic* PFO with special care and with small amounts of foam. There was no special recommendation for patients with known *asymptomatic* PFO. Between both Consensus Meetings, one single report on a transient neurological incident was published [18], so it was important to carefully reconsider the topics of PFO and migraine again. A causal relation between the neurological incident and the injection of sclerosant foam has not been shown so far, but several theories trying to explain the incident exist and were discussed during the 2nd ECMFS, and – independently of and following the 2nd ECMFS – in a moderated internet chat forum [42]. The discussion included statements concerning foam volume, foam quality, used gases and screening procedures prior to treatment. In the discussion, it was mentioned that neurological problems have also been reported after Conventional Liquid Sclerotherapy [32] and that these have been described to occur at a rate of less than 0.01% [53]. Literature provides data after sclerotherapy with air-based foams in low to moderate volumes (1–2 ml or up to 10 ml, respectively), where neurological incidents (including visual disturbances) have been reported at a rate of 0.16% to 0.27% [2, 21]. In another study, after treatment of patients with mean foam volumes of 14.9 or 24.9 ml of an O_2/CO_2-based foam, 6 reports on neurological complications (transient and reversible) such as paraesthesia or visual disorders were reported, corresponding to a rate of 1.4% of neurological incidents [65]. These and previously published data [4, 46] suggest that the rate of neurological problems is higher – compared to liquid sclerosant – *whatever* foam is used, but also that using CO_2/O_2-based foams (instead of air-based foams) does *not* prevent the onset of neurological problems. Having these facts in mind, but also seeking for a high level of safety for patients, the experts passed two consensuses and one description concerning patients with known PFO:

Consensus 20: Known *asymptomatic* Patent Foramen Ovale

Known asymptomatic Patent Foramen Ovale is a *relative* contraindication for Foam Sclerotherapy. In patients with known asymptomatic Patent Foramen Ovale, the following is recommended:

- resting longer in a supine position, from 8 to 30 minutes
- using low foam volumes (2 ml) or using liquid
- avoiding Valsalva manoeuvre
- performing leg elevation of 30 cm.

Description 21: Known *symptomatic* Patent Foramen Ovale

A majority say that a known symptomatic Patent Foramen Ovale is an *absolute* contraindication for Foam Sclerotherapy.

A minority (28%) stated that a known *symptomatic* PFO is a relative contraindication (and suggested the same as in Consensus 20) or saw no contraindication at all.
The necessity of searching for a PFO (with diagnostic tools) vs. thoroughly obtaining anamnestic data was also addressed, and it was the consensus that, based on the number of PFO in the general population, the very few case reports on complications after Foam Sclerotherapy in such patients, other recommendations provided herein and with sufficient patient information, it is not necessary to look for a PFO.

Consensus 21: Looking for a Patent Foramen Ovale before Foam Sclerotherapy

Before Foam Sclerotherapy, it is not necessary to look for a Patent Foramen Ovale.

At the 1st ECMFS, it was stated that there is probably an increased incidence of transient visual disturbances (an equivalent to migraine aura) after treatment with sclerosant foams, as compared to liquid sclerosant treatment. In a large survey performed later, transient visual disturbances were the most frequently recorded adverse event, occurring at a rate of 0.074% for liquid sclerosant treatment or 0.25% for treatment with sclerosant foams, and most often after treatment of RetV and Tel [21]. Again, several theories to explain the possible correlation exist:

– particles or bubbles causing micro-emboli
– missing inactivation of vasoactive substances (because of left-right shunt in PFO patients
– excessive release of vasoactive substances (larger active surface and longer residence time of foam)
– increased vasospastic activity of foam in general.

In a report about one case of migraine ophthalmique after liquid sclerosant injection, vasospastic activity was identified as the most likely reason for the symptoms that developed and resolved a short time later [32]. Since there is no conclusive rationale of any causal relation of migraine-like findings to Foam Sclerotherapy so far, (simple) migraine was not considered a contraindication for Foam Sclerotherapy in general. For safety reasons, some special rules have been proposed nevertheless:

Description 22: History of migraine

A slight majority do not think that known migraine is a contraindication for Foam Sclerotherapy and propose the following:
- using low volumes
- using low concentration
- performing leg elevation
- patient remaining in recumbent position for a longer time

other suggestions were:
- no treatment of Telangiectasia
- using liquid sclerosants

9.2 Thromboembolism and thrombophilia

Acute superficial or deep venous thrombosis (DVT) is a well-known *absolute* contraindication for sclerotherapy in general. Known hypercoagulability or thrombophilia (TP) with a history of DVT are considered *relative* contraindications to sclerotherapy in general. These restrictions were – for reasons of precaution – adopted at the 1st ECMFS for Foam Sclerotherapy. During the preparation of the 2nd ECMFS, the sub-chapter "thromboembolism and thrombophilia" was given higher significance, since with the increased possibilities of varicose vein management with Foam Sclerotherapy, one can expect that more patients with more severe concomitant diseases will be subjected to Foam Sclerotherapy, and hence more detailed recommendations are believed to be helpful in decision-making.
As patients with a previous episode of thromboembolic (TE) events have a relatively high rate of re-thrombosis, it is necessary to carefully assess the risks and benefits of the planned treatment and – in the case of treatment – to avoid triggering the development of subsequent TE incidents.

Description 23: History of thromboembolism

The majority of participants say that a history of thromboembolism is a *relative* contraindication for Foam Sclerotherapy. If in patients with a history of thromboembolism Foam Sclerotherapy is considered, the following is recommended:
- performing adequate low molecular weight heparin (LMWH) prophylaxis
- using low concentrations of sclerosants for foam preparation
- using low volumes of sclerosant foam

additional suggestions were
- performing a full screening for thrombophilia
- estimating the present thrombotic risk (careful medical history and examination).

Besides the patients with a history of TE, there are also patients without a history of TE who are also at high risk of developing a TE, e.g. patients with a combination of thrombophilic factors, diminished mobility, recent (major) surgical procedures and pa-

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tients suffering from active cancers [19, 50].

Description 24: High risk of thromboembolism

The majority of participants say that a high risk of thromboembolism is a *relative* contraindication for Foam Sclerotherapy. If in patients with a high risk of thromboembolism Foam Sclerotherapy is considered, the following is recommended:
- performing adequate low molecular weight heparin (LMWH) prophylaxis
- using low concentrations of sclerosants for foam preparation
- using low volumes of sclerosant foam
- finding a decision case-by-case (considering the risks and benefits according to the indication).

The relevance of thrombophilia (TP) in sclerotherapy is not known. Some participants mentioned that TP might be overestimated as a risk factor for TE following sclerotherapy. Maybe special rare conditions of thrombophilic states are important, especially if connected with other risk factors, such as pregnancy, surgical interventions, immobilisation etc. The most relevant high-risk TP are antithrombine deficiency and antiphospholipid antibodies. Both are associated with a high risk of TE events. Also, patients with combinations of TP like factor-V-Leiden-, prothrombine mutation or protein-C or -S deficiency, or homocygous forms of TP with other factors have a high risk of developing TE events [38].

Since thrombosis after Foam Sclerotherapy is a very rare complication and since the incidence of TP with high risk of TE is also very seldom, it was not recommended to routinely look for TP before Foam Sclerotherapy. Of course, a thorough patient and family anamnesis is advisable.

Description 25: Known thrombophilia

Known thrombophilia (especially with a high risk of thromboembolism) is a *relative* contraindication for Foam Sclerotherapy. If in patients with known thrombophilia Foam Sclerotherapy is considered, the following is recommended:
- performing adequate low molecular weight heparin (LMWH) prophylaxis (acc. to the relevant guidelines)
- performing physical prophylaxis
- using low concentrations of sclerosants for foam preparation
- using low volumes of sclerosant foam
- finding a decision case-by-case (considering the risks and benefits according to the indication).

Consensus 22: Looking for thrombophilia before Foam Sclerotherapy

Before Foam Sclerotherapy, it is not necessary to routinely look for thrombophilia.

For patients with a history of TE (described in Description 23) or patients at high risk (see Description 24 or Description 25), the use of adequate low molecular weight heparin (LMWH) prophylaxis was described in detail in the following consensus (Consensus 23):

Consensus 23: Use of low molecular weight heparin (LMWH) prophylaxis

In patients with a history of thromboembolism and / or in patients with a high risk for thromboembolism, it is recommended to give LMWH at a prophylactic dose for 7 days and follow the specific guidelines for thromboembolic prophylaxis in high-risk patients.

9.3 Other relative and absolute contraindications

Besides the relative and absolute contraindications described so far, there were other questions which explicitly asked about additional contraindications for Foam Sclerotherapy. During the discussion it was mentioned that visual, mental or neurological symptoms after previous Foam Sclerotherapy should be regarded as a *relative* contraindication. Maybe, looking for a PFO would reveal a shunt in those patients, who then would no longer be treated with sclerosant foam, because then the patients would be classified as having a known *symptomatic* PFO.

Description 26: Other *relative* contraindications

A majority say that *relative* contraindications for Foam Sclerotherapy are the same as for Classical Liquid Sclerotherapy, and that, in addition, it is a *relative* contraindication if visual, mental or neurological symptoms have occurred during previous Foam Sclerotherapy.

Likewise, patients with known asymptomatic PFO (who would be considered to have a *relative* contraindication) who would be treated with special care (see Consensus 20), but who developed neurological symptoms during treatment with sclerosant foam, would be judged as "known *symptomatic* PFO" and therefore would be regarded as having an absolute contraindication (see also Description 21).

Description 27: Other *absolute* contraindications

A majority say that known PFO with neurological symptoms following previous Foam Sclerotherapy is an *absolute* contraindication.

10. Compression after Foam Sclerotherapy

Basically, there is no substantial difference between Foam Sclerotherapy and conventional liquid sclerotherapy concerning compression treatment after sclerotherapy: the majority apply compression and have reasons for doing so, a minority simply do not apply compression, and also have reasons for not doing so. There is only little data about the usefulness of compression after liquid Sclerotherapy [59], and besides one additional study [31], no randomised, controlled trial exists at all.

The reasons for or ideas behind applying compression are to keep intravascular clots as small as possible, to reduce symptoms after sclerotherapy, to treat or prevent sequelae (e.g. phlebitis, hyperpigmentation) or to perform prophylaxis against TE in patients at risk. Reasons not to apply compression are to diminish patients' discomfort and non-compliance, the difficulty of really closing the veins and an unproved benefit of compression after sclerotherapy for a couple of indications [39].

Description 28: Compression after Foam Sclerotherapy

A large majority see a necessity of compression after Foam Sclerotherapy in GSV, SSV, Tributaries, Recurrent Varicose Veins, Perforating Veins and Venous Vascular Malformations. There is a tendency for longer compression (3 to 4 weeks) in GSV, SSV and Venous Vascular Malformations. A majority apply compression to the complete leg in GSV, SSV and Recurrent Varicose Veins.
For Tributaries, Perforating Veins, Reticular Veins and Venous Vascular Malformations, compression of the complete leg and local eccentric compression are applied almost equally.

If compression is applied, it can be done "completely" (i.e. the whole leg) or locally (only in the area that has been treated). To increase local pressure on the veins treated, cotton wool pads can be placed under the compression stocking or bandage, also known as "local eccentric compression". This local eccentric compression is usually removed after hours to days, but the ordinary compression is carried on for a certain time (up to 3 to 4 weeks for larger varicose veins or VVM, Fig. 7).

Description 29: Compression material after Foam Sclerotherapy; see Table XIV

The material used for compression usually comprises compression stockings and compression bandages. Both materials are used, sometimes in combination, i.e. a bandage is placed additionally above the stocking, but removed earlier than the compression stocking.

Concerning the differences of compression after Foam and Conventional Liquid Sclerotherapy, it was suggested to wait a few minutes after the injection of foam into large varicose veins before the patient is allowed to stand up or before compression is applied to ensure that the foam remains in place for a sufficiently long time (efficacy criterion) or to avoid dislocation of the foam column (safety criterion) (see also Consensus 16 and Description 20).

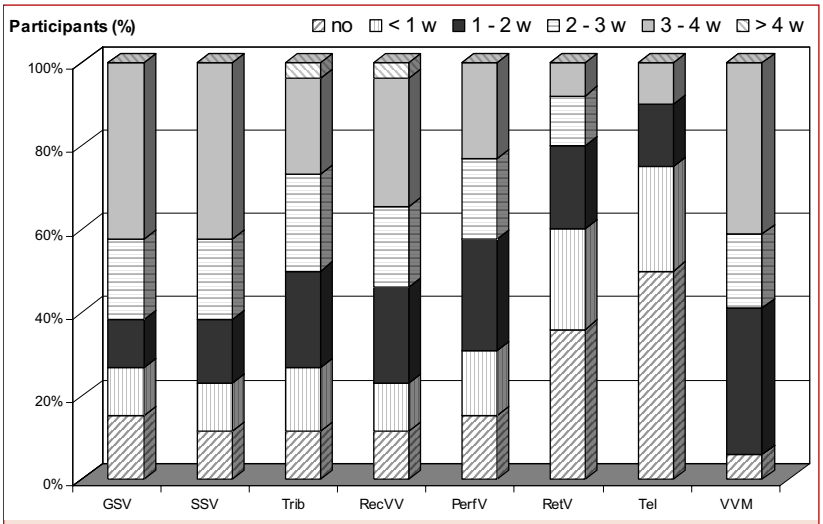

Figure 7: Compression after Foam Sclerotherapy
Number of participants in percent performing "no compression" or "compression" after Foam Sclerotherapy in the different indications indicated. The duration of compression was noted in weeks (w)

Description 30: Time for applying compression

The majority do not apply compression immediately after the treatment of GSV, SSV, Tributaries, Recurrent VV or Perforating Veins, but wait for some minutes (1–10 minutes for GSV or SSV or 1–5 minutes for Tributaries, Recurrent Varicose Veins or Perforating Veins).
For Reticular Veins, Telangiectasia and Venous Vascular Malformations, compression is either applied immediately or after some minutes.

Anyway, during the discussion about compression, it was frequently stated that more studies are needed to clarify the effects of compression after

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Table XIV: Compression material after Foam Sclerotherapy

	stocking only [mmHg]	stocking [mmHg] and bandages	bandages only
GSV	15–40 (30)	20–60 (30)	X
SSV	15–40 (30)	20–60 (30)	X
Trib	15–40 (30)	20–60 (30)	X
RecVV	15–40 (30)	20–60 (30)	X
PerfV	15–40 (30)	20–60 (30)	X
RetV	18–30 (25)		X
Tel	18–25 (22)	30	X
Vasc Malf	15–40 (30)	20–60 (30)	X

Values given are pressures in [mmHg] as ranges
Values in brackets are mean pressure values in [mmHg]
For compression with bandages only, no pressures were indicated (X)
"Stockings only" are used by 15/29 experts
"Bandages only" are used by 5/29 experts
"Stockings and bandages" are used by 13/29 experts
(some experts change the method of compression, depending on the individual case)

sclerotherapy, and especially after Foam Sclerotherapy. In case of the occurrence of phlebitis as a side effect of Foam Sclerotherapy, all experts apply compression.

11. Patient Information

All participants agreed that the patient must be sufficiently informed about the benefits, possible complications and risks of Foam Sclerotherapy before treatment. To comply with this, it is necessary to give information about risks and adverse events of the liquid sclerosing agent (to be used for foam preparation) and in addition, give information about possible changes in the efficacy and safety profile if sclerosant foam is going to be injected. This will help the doctor to obtain informed consent from the patient for the treatment.

Likewise, in addition to the information concerning efficacy which is given to the patient before Conventional Liquid Sclerotherapy, there is additional information which a patient should know prior to Foam Sclerotherapy.

Consensus 24: Patient information concerning risks and side effects

Concerning risks and possible side effects, a patient should be told the same as before Conventional Liquid Sclerotherapy, and, *in addition*, before Foam Sclerotherapy, that there is

- a slightly higher risk of causing hyperpigmentation and inflammation
- a risk of causing (transient) neurological symptoms
- a risk of causing (transient) visual disturbance
- a risk of causing migraine.

Description 31: Patient information concerning safety

Concerning the safety profile, a patient should be told

- that Foam Sclerotherapy is a safe method, especially if the safety precautions are adhered to
- that the method evolved from Conventional Liquid Sclerotherapy
- the recommendations given at the 1st European Consensus Meeting on Foam Sclerotherapy in 2003[7]
- to call the doctor immediately if anything untoward happens
- how to behave after treatment.

Consensus 25: Patient information concerning efficacy

Concerning efficacy, a patient should be told the same as before Conventional Liquid Sclerotherapy, and, *in addition*, before Foam Sclerotherapy

- that the short-term outcomes are very satisfactory
- that some re-treatments may be necessary in some cases, especially when treating large varices
- that Foam Sclerotherapy is more efficient than Conventional Liquid Sclerotherapy.

12. Endovenous Catheter Techniques

Different techniques of endovascular catheter-delivered Foam Sclerotherapy have been published [1, 10, 20, 33, 34, 35, 54, 55, 61]. Some of the authors use regular catheters (e.g. catheters for angiography), others use catheters equipped with one or more balloons (to block the flow of blood and/or foam) and one or more openings for foam delivery. A few authors also try to re-aspirate the foam after a certain time following injection.

Using endovenous catheters may have some theoretical advantages, especially that, after correct placement, it is hard to inadvertently dislocate the tip of the catheter within the vein, that the foam can be delivered very accurately, and that there is no need to hurry injecting the foam, since the foam can be prepared *after* catheter

7 In 2003, it was decided that the following information should be given to the patient additionally:
- Foam Sclerotherapy is a development of an already existing method, using sclerosing agents that have been successfully used for decades.
- In experienced hands the results of this method have proved to be superior in some indications, although the time of experience is shorter than with Conventional Liquid Sclerotherapy.
- With duplex ultrasound guidance there is better control of the injection of large varices.
- There is no difference between Conventional Liquid Sclerotherapy and Foam Sclerotherapy with regard to the instructions to be followed after the treatment given to the patient.

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placement and therefore be injected in a fresh condition. All other techniques of accessing the vein have at least one of these advantages, too. Among the disadvantages, increased costs, longer procedure times and a higher complexity of treatment have been mentioned. The experts at the meeting often stated that they are pretty satisfied with the techniques they are familiar with and that there are no comparative data to show the advantages of using endovascular catheters in Foam Sclerotherapy.

Only a few experts have personal experience in performing endoluminal Foam Sclerotherapy with long catheters. They all use different lengths, materials, diameters and brands, also depending on the indication. Since it was not possible to generalise, it was the opinion that different devices (lengths, diameters etc.) should be available to meet different needs for different indications.

A long discussion, which had already partly taken place elsewhere, arose again when the necessity of a blocking balloon was discussed. It was mentioned that foam or foam remnants – after deflating a balloon within the vein – could be dislocated into the systemic circulation all at once (i.e. foam bolus), whereas an unblocked vein would continuously release foam in small amounts into the systemic circulation. Literature provides no comparative data showing the benefits of using blocking catheters in endoluminal Foam Sclerotherapy.

Description 32: Necessity of a blocking balloon for endovenous long-catheter Foam Sclerotherapy

Based on the current published data, the majority of participants do not see a necessity that an endoluminal catheter for Foam Sclerotherapy should be equipped with a balloon to block junctions.

13. Duplex Ultrasound in Foam Sclerotherapy

The role of (duplex) ultrasound in Foam Sclerotherapy was intensively discussed during the 2nd ECMFS. Duplex ultrasound is important in pre-treatment diagnosis, treatment control or guidance and post-treatment efficacy evaluation or surveillance. Therefore, duplex ultrasound has an impact on a lot of other consensuses and descriptions. Since this topic was so complex, not all aspects could be dealt with during the 2nd ECMFS, and finally a working group was set up. They completed their work after several proposals, ongoing discussions and multiple changes in March 2007.

Description 33: The role of Duplex Ultrasound in pre-treatment diagnosis

In pre-treatment diagnosis of varicose veins, the exact localisation of insufficient Saphenous, Communicating and Perforating Veins is very important. Duplex ultrasound is the accepted gold standard for this purpose.

Duplex guidance during the treatment is thought to be important by a majority of the participants. It helps to confirm the intravascular placement of needles, catheter tips or any other means of vein access. Also, the injected foam can be visualised by ultrasound. Thus, it can be controlled whether foam reaches the region intended to be treated (e. g. saphenofemoral junction). It can also be visualised whether large amounts of foam reach regions not intended to be treated (e.g. muscle veins, deep veins). Thus, duplex guidance can help making a decision concerning the foam volumes to be injected, the patients' position or specific movements the patients should perform. It was decided by all but one expert that duplex guidance during puncture and injection of *non-visible* varicose veins is mandatory, as specified in more detail in Consensus 26.

Consensus 26: Duplex guidance during Foam Sclerotherapy

For the puncture of *non-visible* varicose veins, duplex guidance is an important tool to prevent mispuncture. For direct puncture and injection of non-obvious GSV, SSV, Perforating Veins and non-obvious varicose veins in the groin or in the popliteal fossa, guidance by ultrasound imaging (preferably by duplex) is mandatory. For other non-obvious varicose veins, guidance by ultrasound imaging is recommended.

Duplex ultra-ultrasound plays another important role in the assessment of the therapeutic outcome of Foam Sclerotherapy, i.e. evaluation of treatment efficacy. Timeframes and the roles of clinical evaluation (see chapter 7) and of duplex ultra-ultrasound were intensively discussed. After an appropriate time and after clinical evaluation has been done, duplex ultrasound evaluation should be performed to control the efficacy in certain indications. Duplex is the most favourable tool to evaluate the results of Foam Sclerotherapy in non-visible veins. The criteria are summarised in Consensus 27.

Consensus 27: Duplex criteria to evaluate the effects of Foam Sclerotherapy

Duplex criteria to evaluate the therapeutic effects of Foam Sclerotherapy in the treated veins are

- occlusion – patency
- length of occlusion
- flow – no flow
- antegrade flow – reflux (> or < 1 sec)
- compressibility of the vein
- diameter of the vein
- morphologic changes (fibrosis / thickening of the vein wall)
- absence of vein.

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The findings of duplex, the clinical findings and the symptoms can be arranged according to the definitions of Consensus 28, thereby allowing the therapeutic outcome, not only of Foam Sclerotherapy but also of other treatment modalities *to be graded*, enabling a better comparability between different treatments.

Consensus 28: Definition / grading of therapeutic effects of Foam Sclerotherapy; see Table XV

The question, in which patients (following the grading of Consensus 28) re-injection is necessary or useful, was discussed, but could not be answered during the 2nd ECMFS. It was mentioned that there is no reliable data to answer this question at present. On the other hand, the experts made clear during the discussions that patients with a grading 2a or 2b would barely be re-injected, and that in patients with grading 2c re-injection would sometimes be done. In patients with grading 1, re-injection often depends on the clinical situation or on the symptoms, and in most of the cases most of the experts would re-inject. In patients with grading 0, there is a clear indication for re-treatment (see Description 15). In published literature, it has been shown that the rate of successful treatments

Table XV: Definition / grading of therapeutic effects of Foam Sclerotherapy

Grading / Name	Duplex findings		Clinical	Symptoms
2 FULL SUCCESS	NO REFLUX	a) complete disappearance of the treated vein or "fibrous cord" (incompressible echogenic cord in the position of the treated vein) b) complete occlusion (incompressibility) of the treated vein segment c) patency of the treated vein segment with reduced diameter and *antegrade* flow	normalised (i.e. no visible varices)	absent or improved
1 PARTIAL SUCCESS	REFLUX < 1 sec.	partial incompressibility and partial occlusion of the treated vein segment and diameter reduction	normalised or improved (i.e. smaller visible varices)	absent or improved
0 NO SUCCESS	REFLUX > 1 sec. or unchanged	complete (or incomplete) patency and/or no change in diameter	unchanged or worsened (i.e. larger varices and / or clinical CEAP deterioration)	unchanged or worsened

Additional information
- Duplex evaluation is performed in an upright position
- The length of the occluded vein must be compared with the length of the insufficient part of the vein which was injected with the aim of occlusion (before injection it should be decided which part of the vein is intended to be treated). This is important for the question whether the "whole vein" is occluded after treatment
- Reflux is measured with the Valsalva manoeuvre or distal compression / decompression
- With reference to symptoms – if applicable – more differentiated and standardised symptom scores like the VSS can be used, otherwise the VAS (visual analogue scale 1–10) can be very useful and simple
- With reference to clinical findings – if applicable – more differentiated and standardised classifications such as CEAP can be used
- The definitions and gradings are applicable for all endovenous procedures (endovenous laser, radiofrequency ablation and sclerotherapy) and should allow comparison
- In the case of simultaneous treatment for medical and for aesthetic reasons, two separate questionnaires should be used
- The number of treatments (injections, sessions) and the kind of treatment used should be recorded

after ultrasound-guided Foam Sclerotherapy can be increased if re-injection is performed in re-opened veins after initial treatment success or non-occluded veins after the first treatment ("secondary success") [37]. The natural development of "partially successfully" treated veins (grading 1) is not clear: they could re-open completely, become occluded over the course of time, or remain "partially successfully", with or without re-injection. Further evaluation of the outcome of re-injected vs. non-re-injected veins with grading 1 is of particular interest. For patients with grading 0 or 1 *before* and grading 2a, b or c *after re*-injection, a term like "primary assisted complete success" would better describe the situation rather than "secondary success".
Besides evaluation of the treatment success, duplex ultrasound is the method of choice to exclude or confirm complications or disease progression.

Description 34: The role of Duplex Ultrasound after Foam Sclerotherapy

In follow-up after Foam Sclerotherapy, duplex is the method of choice to exclude complications such as deep venous thrombosis.

14. Miscellaneous

One more subject was discussed during the 2nd ECMFS: clot removal after Foam Sclerotherapy. The experience of most of the participants was that hyperpigmentation and local hardening in the course of the vein treated are more common after Foam Sclerotherapy. In CLS, clot removal after 1 to 4 weeks is usually recommended, predominantly to reduce the rate of hyperpigmentation [30]. This recommendation has been adopted by the experts for Foam Sclerotherapy, because there is a demand for reducing the rate of hyperpigmentation as much as possible.

Consensus 29: Clot removal after Foam Sclerotherapy

In case of clot formation in the superficial veins after Foam Sclerotherapy, clot removal is recommended.

Acknowledgment

The authors wish to express their special thanks to all the participating and involved experts for their valuable help in this very time-consuming and laborious procedure of finding all the consensuses and descriptions. Special thanks to the members of the working groups (Attilio Cavezzi, Phillip Colderidge-Smith, Jean-Jérôme Guex, Claudine Hamel-Desnos, Nick Morrison, Bernhard Partsch, Hugo Partsch and Eberhard Rabe), who had to continue finding agreements even after the meeting. Lots of thanks also to Petra Düsterhöft for getting the latest relevant literature, and Hugo Partsch for valuable advice in editing this publication.
The authors appreciate that the Consensuses and Descriptions of the 2nd ECMFS are currently implemented into the Guidelines for Sclerotherapy 2007 of the German Society of Phlebology. The complete guidelines are available at www.phlebology.de.
Finally, the authors acknowledge the support of Kreussler-Pharma for covering travel expenses and accommodation of the participants and for the meeting locations.

Summary

Rationale

The spread of Foam Sclerotherapy has resulted in the renaissance of sclerotherapy as a non-invasive treatment method for varicosis. The use of sclerosant foam for various forms of varicosis has now become established world-wide as safe and effective. An expanded European expert committee meeting in April 2006, in Tegernsee was prompted by new findings and continuous further development of the method, but also because it had not been possible to consider all the relevant aspects of Foam Sclerotherapy in depth at the first meeting.

Objectives

To revise and update the results of the 1st European Consensus Meeting and to include new, important topics in the development of Foam Sclerotherapy. To provide practical information for less experienced colleagues.

Methodology

The 29 participants were sent a comprehensive questionnaire in advance covering all the relevant aspects of Foam Sclerotherapy. The organisers drew up various preliminary statements on the basis of the results. During the meeting itself the participants revised and/or approved and/or rejected these statements. An additional analysis of the questionnaire data also enabled preparation of an illustrative description of the broad spectrum of individual procedures used in this form of treatment.

Results

Foam Sclerotherapy has become an established treatment option for varicosis and has undoubtedly improved the management of varicose veins. European experts met in Tegernsee for a second time to revise and expand their previous recommendations. In addition, individual working groups focused extensively on important issues. The current consensuses, recommendations and descriptions of the individual aspects of the methods concern such issues

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as the indications for Foam Sclerotherapy, concentration and volume of the liquid sclerosants, relative and absolute contraindications, access and puncture options as well as clinical and ultrasound-guided recording of the treatment results. This final document reflects the experts' opinions on the principles of the effective and, above all, safe use of sclerosant foam for various indications and correct monitoring of the results of Foam Sclerotherapy.

Zusammenfassung

Hintergrund
Die Verbreitung der Schaumsklerotherapie hat zu einer Renaissance der Sklerotherapie als nicht-invasive Methode der Behandlung der Varikose geführt. Die Verwendung von Sklerosierungsschaum ist bei verschiedenen Formen der Krampfadererkrankung mittlerweile weltweit als sicher und wirksam etabliert. Durch hinzugewonnene Erkenntnisse, kontinuierliche Weiterentwicklungen der Methodik, aber auch, weil nicht alle relevanten Aspekte der Schaum-Sklerotherapie während eines 1. Treffens umfassend bearbeitet werden konnten, fand im April 2006 ein 2. Treffen eines erweiterten europäische Expertengremiums am Tegernsee statt.

Ziele
Revision bzw. Aktualisierung der Ergebnisse des 1. Europäischen Konsensus-Treffens und Aufgreifen neuer wichtiger Themen in der Entwicklung der Schaum-Sklerotherapie. Bereitstellung von praktischen Hinweisen mit Empfehlungscharakter für weniger erfahrene Kolleginnen und Kollegen.

Methodik
Im Vorfeld wurde den 29 Teilnehmern ein umfangreicher Fragebogen zu allen relevanten Aspekten der Schaumsklerosierung zugesandt. Auf Basis der Befragungsergebnisse formulierten die Organisatoren eine Reihe von vorläufigen Stellungnahmen. Während des eigentlichen Treffens wurden diese Stellungnahmen von den Teilnehmern diskutiert, gegebenenfalls überarbeitet und entweder bestätigt oder verworfen. Eine zusätzliche Auswertung der Fragebogendaten ermöglichte darüber hinaus auch die darstellende Beschreibung der groflen Palette einzelner unterschiedlicher Vorgehensweisen bei dieser Therapieform.

Ergebnisse
Die Schaumsklerosierung ist zu einer etablierten Behandlungsalternative bei Krampfadern geworden und hat zweifelsfrei das Management der Krampfadererkrankung verbessert. Zum zweiten Mal trafen sich Europäische Experten am Tegernsee, um ihre bisherigen Empfehlungen zu überarbeiten und zu ergänzen. Einzelne Arbeitsgruppen konzentrierten sich zusätzlich auf besonders wichtige Themen. Die aktuellen Consensi, Empfehlungen und Beschreibungen der einzelnen Aspekte der Methode betreffen unter anderem die Bereiche Indikationen zur Schaum-Sklerosierung, Konzentrationen und Volumina der Sklerosierungsmittel, relative und absolute Kontraindikationen, Zugangs- bzw. Punktionsmöglichkeiten sowie klinische und ultraschall-gestützte Erfassung des Therapieerfolges. Dieses Abschlussdokument widerspiegelt die Meinungen der Experten hinsichtlich der Prinzipien für eine wirkungsvolle und vor allem sichere Anwendung von Sklerosierungsschaum bei verschiedenen Indikationen und einer sachgerechten Erfolgskontrolle der Schaum-Sklerosierung.

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