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Compression Sclerotherapy for Primary Valvular Insufficiency –From Liquid to Foam–

Takashi Yamaki, MD

The history of sclerotherapy of varicose veins of lower extremities dates back to 1840's. The use of stronger sclerosants thereafter led to serious complications, and the use of sclerotherapy decreased for varicose veins. However, sclerotherapy again became popular after introduction of safer sclerosant and compression sclerotherapy. After introduction of sclerosing foam in mid 1990's, many phlebologists are now in favor of the use of sclerosing foam instead of the use of sclerosing liquid. However, few studies have focused on the efficacy of sclerosing foam compared with that of sclerosing liquid in sclerotherapy of venous insufficiency. In Europe, the 1st and 2nd European Consensus Meetings on Foam Sclerotherapy (ECMFS) were already taken place in Germany. In this review, we discuss the efficacy of sclerosant foam in comparison with liquid form. Furthermore, solved and unsolved questions on safety aspect of foam sclerotherapy are also discussed.

Key words: superficial venous insufficiency, varicose veins, ultrasound-guided foam sclerotherapy

INTRODUCTION

Polidocanol (hydroxy(poly)tetradodecane: POL) is originally developed as a local anesthetic, and is now most frequently used detergent sclerosing solution in Europe. In Japan, it is the only sclerosant that has been approved by the Japanese Ministry of Health, Labour and Welfare, in 2006. It is also commonly used in the United States, however, it is not yet approved by Food and Drug Administration (FDA) as a pharmaceutical product. After introduction of sclerosing foam, many phlebologists are now in favor of the use of POL-foam (POL-F) instead of the use of POL-liquid (POL-L). However, few studies have focused on the efficacy of POL-F compared with POL-L in sclerotherapy of venous insufficiency.

History of Foam Sclerotherapy

Historically, McAusland first proposed the use of “froth” in telangiectasia. The foam obtained using his technique was simply shaking the rubber-capped bottle that was filled with sodium morrhuate, and the froth was aspirated into a syringe.1 In 1944, Orbach described air-block method.2 He used this technique for only smaller and medium-sized varicose veins. He recommended the conventional technique, without air-block technique, for larger veins. In 1949, Karl Sigg applied the air-block technique for larger veins, and reported more than 4,000 treatments performed without complications.3 In 1950, Orbach recalled his air-block technique which allowed him to improve the success rate by 10%.4 Using his technique, however, only 20% of the sclerosant was transformed into foam with bubbles of relatively large and irregular caliber. And the side effects caused by this method lead to its abandonment. Therefore, foam sclerotherapy did not become popular till mid 1990s’ after the introduction of new methods of transforming sclerosing solutions.

There have been several different methods reported in the production of a foam form. In 1995, Cabrera proposed the injection of a physiologic gas (CO₂) into the
scribed his “on-site” production technique in the article that generated a simple foam with air in glass syringe.7) Henriet reported his experience using Monfreux’s technique for minor varices.8) He insisted that the foam differs from that produced by Orbach in terms of the regularity, stability and durability. In 1998, Benigni and Sadoun proposed mixing the sclerosing agent with air in a disposable plastic syringe.9) They reported a study comparing the short term efficacy of the 0.25% polidocanol foam with a liquid form in the treatment of telangiectases.10) Mingo-Garcia developed a special device for producing a foam form with compressed air.11) In 2000, Tessari reported a new method for the production of foam with two syringes connected with a three-way stopcock, named as “Tessari method.” Italian colleagues rapidly adopted this technique, and it has been widely accepted in producing a stable foam.12) In 2000, Sica and Benigni reported 3-year experience with duplex-guided sclerotherapy on saphenous trunks using tetradecyl sulfate and demonstrated the advantages of foam compared with liquid form.13) Similarly in 2000, Frullini and Cavazzì demonstrated their experience with duplex-guided foam sclerotherapy and evaluated its effects and safety.14)

**Producing Sclerosant Foam**

Three methods are recommended for preparation of stable foam according to the 1st European consensus meeting on foam sclerotherapy (ECMFS).3) Monfreux described a method necessitating a glass syringe, which produced small quantities of POL foam, which he used in a series of patients with truncal varicose veins.8) Monfreux generated an absolute negative pressure by placing a cap on the syringe. Although all concentrations of sclerosants can be used with this method, a defined ratio of gas and sclerosant or a defined bubble size cannot have been predicted yet.16) Sclerosing foam is easily produced by Tessari’s method using two syringes and a three-way stopcock. Basically, 1% and 3% POL are used. A syringe of 5 ml was filled with 0.5 ml of POL. And 2.0 ml of air was aspirated with another syringe of 5 ml. Two syringes were attached by a three-way stopcock, and the stable sclerosing foam was obtained by mixing them through multiple passages between the two syringes.

However, foams had a different consistency and inhomogenous flow behavior if minor changes were made during preparation. In laboratory experimental studies, efforts were made to find the best possible combination of connector type, syringe size, liquid-to-gas ratio, sclerosant concentration and manufacturing instruction. The result is known as “double-syringe system (DSS)” or “Tessari/DSS.”17, 18) Tessari/DSS 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-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’ plunger) and again 7 times (without additional pressure).19)

At the 2nd ECMFS, the method of Tessari and the Tessari/DSS are recommended for all indications. Only a few experts were found to use Monfreux’s technique for reticular and telangiectatic veins.19)

**Patients Selection**

Generally, patients with primary valvular insufficiency with reflux in the superficial and perforating veins are good candidates for foam sclerotherapy. Foam sclerotherapy can be carried out successfully in almost any patient with clinically significant venous disease no matter how elderly, frail, obese or ill they are.20) And in principal, all vein calibers with primary valvular insufficiency and recurrent varicose veins are suitable for foam sclerotherapy. The larger the diameter of the vein, the more viscous the foam should be to obtain better results. And lower diameter threshold exists using viscous foams. On the contrary, an upper diameter threshold is recognized with liquid forms although no lower caliber limit exists.21)

Compression sclerotherapy is best performed with the patients on an ambulatory basis. Therefore, at the 1st ECMFS, sclerotherapy was not considered to be done in patients who need long-distance travel and who are at bedrest. Patients with the known allergic reaction to sclerosant and the previous history of deep vein thrombosis and/or pulmonary embolism should not be treated with sclerotherapy. Patients who have the known thrombophilia, family history of thromboembolism, and severe arterial insufficiency of the limbs (stage 3 or 4) are also excluded from the treatment using sclerosing solutions. Patients who have systemic disease and hyperthyroidism are absolute contraindications for sclerotherapy.22)
use of restricted amounts of foam is recommended in symptomatic Patent Foramen Ovale (PFO) patients. On the contrary, at the 2nd ECMFS, a known symptomatic PFO is considered as an absolute contraindication for foam sclerotherapy. In addition, a known asymptomatic PFO is a relative contraindication for foam sclerotherapy. However, it is not necessary to look for a PFO before foam sclerotherapy.19)

**DIAGNOSTICS BEFORE SCLEROTHERAPY**

Proper evaluation of the patients is a key to obtain successful results. Diagnostic examination includes study of medical history, clinical examination and Doppler ultrasonography. Nowadays, duplex scanning is considered as an important frontline test in patients with primary valvular insufficiency. Duplex scanning can detect distribution of venous reflux as well as the extent of reflux. Over 90% of patients with primary valvular insufficiency have superficial venous insufficiency with or without deep and perforating vein incompetence.22) Even in patients with combined superficial and deep vein insufficiency, ablation of reflux in the superficial venous system may lead to abolishment of deep vein reflux.23, 24) Therefore, foam sclerotherapy is a good treatment option for these patients.

Additionally, functional testing can detect improvement of venous function. Recent studies have shown that air plethysmography (APG) can provide quantitative measurements of venous reflux, and the amount of reflux is closely related to disease severity.25, 26) Combination of non-invasive diagnostic testing is also useful in the follow-up patients after sclerotherapy.

**DUPLEX-GUIDED SCLEROTHERAPY**

Theoretically, duplex-guided sclerotherapy should give improved results when treating a refluxing great saphenous vein (GSV). Using the duplex guidance, safe injections are carried out by an experienced sclerotherapist.27, 28) Bishop and associates reported a GSV obliteration rate of only 6% when treating the refluxing GSV without duplex guidance.29) On the contrary, Kanter and associates demonstrated recanalization rates of 24.1% at 1 year and 35.7% at 2 year with duplex-guided sclerotherapy, which appears to be superior to that achieved by conventional sclerotherapy.30) At the moment, wide range of different practices are being performed in sclerotherapy. In Consensus Conference on sclerotherapy held in Padua in 1994–1995, duplex-guided sclerotherapy was recommended for lesser saphenous varicose veins, anterior saphenous varicose veins, recurrent varicose veins, perforators, and obese patients.31) No agreement had been reached regarding the need for duplex-guided sclerotherapy, or the advantages of this treatment, for the GSV incompetence.31) At the ECMFS, however, duplex guidance was recommended because foam is easily identified by duplex scanning, and the initial effects are visible in real time.15, 19)

**Comparative Study Between Duplex-Guided Foam Sclerotherapy and Liquid Sclerotherapy**

To confirm the safety and efficacy of duplex-guided POL-F sclerotherapy (DGFS), and to compare the preliminary results of hemodynamic changes between DGFS and duplex-guided POL-L sclerotherapy (DGLS), the author conducted comparative study in patients with superficial venous insufficiency.32)

**Patients**

Between 2001 and 2002, 77 limbs in 77 patients with isolated GSV incompetence were selected for duplex-guided sclerotherapy. The patients comprised 15 males and 62 females, ranging in age from 21 to 84 years (mean 54.6 years). Of these, 37 limbs were treated with DGFS and remaining 40 limbs were treated with DGLS. All of the patients’ lesions were classifiable into no signs of venous disease (CEAP C0), telangiectases or reticular veins (C1), varicose veins (C2), edema (C3), changes in the skin and subcutaneous tissue (C4a, b), or chronic ulcers (C5 and C6). Patients with myocardial ischemia, arterial insufficiency with ankle brachial index of less than 0.8, and active thrombophlebitis, and these with active ulcers were excluded. The follow-up period of the patients was 12 months.

**Duplex scanning**

Pretreatment examination was performed to detect venous reflux at the sapheno-femoral junction (SFJ) and in the GSV. Venous reflux was assessed with the patients in a standing position, by applying distal manual compression followed by sudden release. Venous reflux was considered to be present if the duration of reflux exceeded 0.5 sec. Venous obstruction and recanalization were screened by serial posttreatment duplex examination.

**Air plethysmography**

Pretreatment air plethysmography (APG) measurements were obtained including venous filling index (VFI), ejection fraction (EF), and residual venous frac-
tion (RVF). Posttreatment APG analysis was performed 3, 6, 9 and 12 months after the sclerotherapy.

**Duplex-guided sclerotherapy**

The sclerosing foam was produced by Tessari’s method using 1% and 3% POL (Fig. 1). Each visible varicose tributary vein draining into the GSV was injected first (Fig. 2), with 2 ml of 1% POL-F or 1% POL-L. Then 0.5 ml of 3% POL-F or 3% POL-L were injected under duplex guidance, starting 3–4 cm distal to the SFJ, and the second injection was made 5 to 10 cm distal to the initial point with 0.5 ml of 3% POL-F or 3% POL-L (Fig. 3, 4). Compression pads and elastic bandages were applied after the sclerotherapy, and kept on continuously for the first two days. All patients were encouraged to ambulation after the treatment. On postsclerotherapy day 3, elastic bandages and compression pads were removed, and Class II thigh-high compression stocking was applied.

**Statistical analysis**

Wilcoxon’s nonparametric rank sum test and chi-square analysis or Fisher’s exact test were used to evaluate differences between groups of patients. Statistical significance was defined as $p < 0.05$.

**Results**

There were no significant differences in age, male-to-female ratio, and clinical presentation between the two groups, and CEAP clinical classes were all matched (Table 1).
The incidence of the venous reflux at the 12-month follow-up point was shown in Table 2. Duplex scanning demonstrated complete occlusion in the GSV for DGFS (Fig. 5) in 25 limbs (67.6%), which was a significantly higher proportion than for the DGLS (7 limbs, 17.5%, \( p < 0.0001 \)). There was no statistically significant difference in the proportion of partial recanalization without reflux (\( p = 0.580 \)). Similarly, there was no significant difference in the proportion of partial recanalization with reflux between the two groups (\( p = 0.171 \)). Complete recanalization with reflux was detected in 5 (13.5%) in DGFS group, and 22 (55%) in DGLS group, which was statistically significant (\( p = 0.0001 \)). The recurrent varicose veins were defined when the varicose veins reappeared in area previously treated successfully, and were found in 3 patients (8.1%) in DGFS group and 10 (25%) in DGLS group. This was statistically significant (\( p = 0.048 \)).

Table 3 demonstrates the pre-and posttreatment APG examinations. The pretreatment APG examinations showed reflux in both groups (4.34 ± 2.22 ml/sec and 4.39 ± 2.53 ml/sec, respectively). In DGFS, VFI values remained normal during the subsequent follow-up examinations, whereas in DGLS, VFI began to deteriorate, and there was a significant difference at 6 months be-

### Table 1  Baseline characteristics of the study patients (derived from reference 32)

<table>
<thead>
<tr>
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<th>DGFS n = 37</th>
<th>DGLS n = 40</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>54.3 ± 13.9</td>
<td>54.8 ± 14.7</td>
<td>0.617( ^a )</td>
</tr>
<tr>
<td>Female sex (%)</td>
<td>30 (81.1)</td>
<td>32 (80)</td>
<td>0.905( ^b )</td>
</tr>
<tr>
<td>CEAP clinical class*</td>
<td></td>
<td></td>
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<tr>
<td>( C_2 ) (%)</td>
<td>27 (73.0)</td>
<td>31 (77.5)</td>
<td>0.645( ^b )</td>
</tr>
<tr>
<td>( C_3 ) (%)</td>
<td>2 (5.4)</td>
<td>4 (10)</td>
<td>0.577( ^b )</td>
</tr>
<tr>
<td>( C_{a,b} ) (%)</td>
<td>5 (13.5)</td>
<td>3 (7.5)</td>
<td>0.388( ^b )</td>
</tr>
<tr>
<td>( C_5 ) (%)</td>
<td>3 (8.1)</td>
<td>2 (5)</td>
<td>0.580( ^b )</td>
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</table>

There were no statistical differences in age, gender, and CEAP clinical manifestations between the two groups.

DGFS: duplex-guided polidocanol-foam sclerotherapy
DGLS: duplex-guided polidocanol-liquid sclerotherapy

\*CEAP Clinical classification: \( C_0 \), no visible or palpable signs of venous disease; \( C_1 \), telangiectases, reticular veins; \( C_2 \), varicose veins; \( C_3 \), edema without skin changes; \( C_4 \), changes in the skin and subcutaneous tissue; \( C_5 \), healed ulcer; \( C_6 \), active ulcer.

Values expressed as mean ± SD.

\( ^a \) Wilcoxon’s non-parametric rank sum test.

\( ^b \) Pearson’s \( \chi^2 \) test or Fisher’s exact test.

#### Table 2  Incidence of occlusion, recanalization, and recurrence rate after treatment (derived from reference 32)

<table>
<thead>
<tr>
<th></th>
<th>DGFS n = 37</th>
<th>DGLS n = 40</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occluded (%)</td>
<td>25 (67.6)</td>
<td>7 (17.5)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Partial recanalization with no reflux (%)</td>
<td>3 (8.1)</td>
<td>2 (5)</td>
<td>0.580</td>
</tr>
<tr>
<td>Partial recanalization with reflux (%)</td>
<td>4 (10.8)</td>
<td>9 (22.5)</td>
<td>0.171</td>
</tr>
<tr>
<td>Complete recanalization with reflux (%)</td>
<td>5 (13.5)</td>
<td>22 (55)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Recurrence (%)</td>
<td>3 (8.1)</td>
<td>10 (25)</td>
<td>0.048</td>
</tr>
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</table>

There was a statistically higher proportion of occlusion in DGFS, and there was a statistically higher proportion of reflux in DGLS. Recurrence was statistically predominant in DGLS.

DGFS: duplex-guided polidocanol-foam sclerotherapy, DGLS: duplex-guided polidocanol-liquid sclerotherapy
There was no significant difference in EF value between pre- and post-treatment examinations in both groups. At 9 months, there was a significant difference in RVF between the two groups, and RVF value continued to be improved in DGFS (p = 0.033). No adverse events were found using both foam and liquid sclerosing solutions in this series.

**Recent Randomized Controlled Trials Between Foam And Liquid**

The results of recent randomized controlled trials (RCTs) show a significantly higher response rate for sclerosant foam compared to liquid foam for treatment of the incompetent GSV. The response rate differed greatly between study centers, as shown in Table 4. Some of the published RCTs were a single center's, in some trials significantly higher foam volumes were used, sometimes smaller GSVs were treated or tributaries were injected during the same session.32–37)

**Safety Aspects of Foam Sclerotherapy**

Because of its efficacy and safety, DGFS has gained

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Table 3  Comparison of hemodynamic variables before and after treatment (derived from reference 15)

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<tr>
<th></th>
<th>Pretreatment</th>
<th>3 Months</th>
<th>6 Months</th>
<th>9 Months</th>
<th>12 Months</th>
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<tr>
<td><strong>Venous Filling Index (VFI), ml/s</strong></td>
<td></td>
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<tr>
<td>DGFS</td>
<td>4.3 ± 2.2</td>
<td>1.4 ± 0.4</td>
<td>1.1 ± 0.4*</td>
<td>1.2 ± 0.6†</td>
<td>1.2 ± 0.8*</td>
</tr>
<tr>
<td>DGLS</td>
<td>4.4 ± 2.5</td>
<td>2.3 ± 1.6</td>
<td>2.2 ± 0.6</td>
<td>2.2 ± 0.6</td>
<td>2.3 ± 0.7</td>
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<tr>
<td><strong>Ejection Fraction (EF), %</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DGFS</td>
<td>51.0 ± 22.9</td>
<td>55.8 ± 14.6</td>
<td>54.4 ± 20.7</td>
<td>51.2 ± 16.8</td>
<td>52.0 ± 13.5</td>
</tr>
<tr>
<td>DGLS</td>
<td>47.7 ± 18.5</td>
<td>58.1 ± 16.6</td>
<td>54.2 ± 40.7</td>
<td>51.9 ± 39.4</td>
<td>50.7 ± 40.4</td>
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<tr>
<td><strong>Residual Venous Fraction (RVF), %</strong></td>
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<td></td>
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<tr>
<td>DGFS</td>
<td>39.6 ± 19.9</td>
<td>28.6 ± 9.2</td>
<td>26.9 ± 22.8</td>
<td>21.2 ± 22.5‡</td>
<td>22.7 ± 26.1‡</td>
</tr>
<tr>
<td>DGLS</td>
<td>36.7 ± 19.8</td>
<td>35.8 ± 16.5</td>
<td>37.0 ± 14.6</td>
<td>35.6 ± 22.8</td>
<td>39.5 ± 16.8</td>
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</table>

*Foam versus Liquid, p < 0.0005
†Foam versus Liquid, p < 0.0003
‡Foam versus Liquid, p < 0.033

VFI began to deteriorate in DGLS, and there was a significant difference at 6 months between the two groups. At 9 months, there was a significant difference in RVF between the two groups, and RVF value continued to be improved in DGFS.

DGFS: duplex-guided polidocanol-foam sclerotherapy, DGLS: duplex-guided polidocanol-liquid sclerotherapy

Fig. 5  Post-sclerotherapy duplex scanning showing complete occlusion of the above-knee great saphenous vein.
great popularity as a minimally invasive treatment for varicose veins, and large case series have been reported. The characteristics of foam sclerosants may explain their greater capacity and irritant nature. Foam sclerosants can displace the blood and adhere better to the walls of veins. However, recent reports have focused attention on the safety of foam for this purpose. Compared to liquid sclerosant, foam sclerosant shows a greater tendency to provoke inflammation, and is consequently associated with mild adverse effects including pain, inflammatory signs, and skin pigmentation. Furthermore, neurologic complications including transient visual disturbance, transient confusion, and even cerebral infarction have been described.

Gas mixture

The gas mixture used to create the bubbles might also be a factor provoking air embolism. Air has been commonly employed, but a more physiological gas might have certain advantages. Bubble life is shorter if the oxygen concentration within the bubble is increased and the nitrogen concentration is decreased. Morrison et al. compared the incidence of side effects between carbon dioxide foam and air-based foam. Concerning dizziness, they found a significant incidence of 12% with air-based foam, decreasing to 3% with carbon dioxide-based foam. Overall, the proportion of patients describing side effects decreased from 39% to 11% as carbon dioxide replaced air for foam preparation ($p < 0.001$).

**Foam volume**

The injected volume of sclerosant foam could also affect the incidence of side effects. A recent European consensus statement recommended 10 ml per session, but different published reports have cited volumes ranging from 3 ml up to 30 ml. A case of stroke was reported with DGFS for GSV incompetence employing 20 ml of POL-foam prepared by the Tessari method. Theoretically, an air embolism can be fatal if a volume of $> 1$ ml/kg is entrained into the venous system, but can cause problems with a volume as small as 50 ml. At lower foam doses, the total gas load of the bubbles is better solubilized, and bubbles may become well separated spatially, reducing coalescence. However, another report has stated that there is no available evidence to suggest that larger volumes are associated with any increased risk to patients receiving DGFS. Our study showed that multiple injections of $< 0.5$ ml 1% POL-F rather than a few injections of $> 0.5$ ml 1% POL-F per injection could reduce the amount of foam sclerosant and the risk of the sclerosant entering the deep veins in patients with superficial venous insufficiency.

**Body position**

Leg elevation during DGFS would prevent foam from entering the deep venous system. In the elevated leg position, the foam will ascend to more distal parts of the
vein, and eventually be able to close incompetent saphenous side branches or tributaries. The ECMFS statement recommended elevation of the leg especially for treatment of larger veins. Hill et al. compared the utility of three commonly used techniques for reducing sclerosant foam migration during DGFS: DGFS while lying supine with application of digital pressure at the SFJ, DGFS while the leg is elevated to 30 degrees with application of digital pressure at the SFJ, and DGFS while the leg is elevated to 30 degrees without application of digital pressure at the SFJ. They concluded that DGFS was best performed while the leg is elevated without digital pressure at the SFJ to avoid migration of sclerosant foam.

**Presence of patent foramen ovale**

At the On-Line International Event on Sclerosing Foam and Patent Foramen Ovale, further procedures were recommended to prevent possible neurologic complications. These included requesting patients not to dress or put on shoes and stockings by themselves, avoiding the Valsalva maneuver and constipation before the procedure. However, the Committee did not reach a final conclusion as to whether there was a clear relationship between clinical events and the use of foam. While chronic cerebral damage resulting from PFO has been suggested, there has been no clear evidence of any acute cerebral effects resulting from injection of foam.

**CONCLUSION**

After the introduction of foam form of sclerosing solution, foam sclerotherapy rapidly gained its popularity. DGFS is a safe and effective treatment for superficial truncal saphenous incompetence as well as for varicose tributary veins. However, further studies may be necessary in order to devise better DGFS techniques, including factors such as foam production, the optimal volume of foam, the use of physiologic gases, and more effective and safe injection techniques.

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