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# Microfoam Ultrasound-Guided Sclerotherapy of Varicose Veins in 100 Legs

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**OBJECTIVE.** To demonstrate the efficacy of duplex-guided foam sclerotherapy measured against patient symptom relief and quality of life.

**METHODS.** An analysis was performed of 100 randomly chosen legs with varicose veins treated with ultrasound-guided foam sclerotherapy with a mean follow-up of 22.5 months.

**RESULTS.** An average number of 2.1 treatments using an average of 8.7 mL of foam sclerosing solution were required

to close incompetent varicose veins. Thirty-one percent of leg varicose veins required a second treatment at 3 months; 100% of patients felt that their legs were successfully treated with resolution of all symptoms in 85% and resolution in all varicose veins in 92%.

**CONCLUSION.** Ultrasound-guided foam sclerotherapy is effective in treating varicose veins with high patient satisfaction with results and improvement in quality of life.

*J. M. BARRETT, FRNZCGP, B. ALLEN, FRACR, A. OCKELFORD, FRNZCGP, AND M. P. GOLDMAN, MD HAVE INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.*

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MICROFOAM ULTRASOUND-GUIDED sclerotherapy (UGS) studies have clearly demonstrated effectiveness in closure of saphenous trunks.<sup>1-4</sup> This retrospective study reviews microfoam UGS treatment for varicose veins in 100 legs from a clinical perspective and from a patient quality of life perspective. The authors have treated a total of 2500 legs with microfoam UGS.

## Methods

One hundred randomly selected legs were analyzed retrospectively with an average follow-up after treatment of 22.5 months (range of 20 to 26 months).

Patients were asked to complete a "quality of life" survey and patient satisfaction survey and were reviewed clinically by Drs. Barrett and Allen with visual assessment and Duplex scanning.

Selection criteria for the study were as follows: (1) Pretreatment truncal incompetence in primary greater saphenous or short saphenous veins as defined by a reflux of more than 0.5 seconds was documented by Duplex/Doppler ultrasound scanning. (2) A Tessari microfoam technique was done using sodium tetradecyl sulfate (STS) 3% in a ratio of 1-mL STS to 3 mL air for saphenous trunks and varying concentrations of

microfoam polidocanol depending on the size of the saphenous branches and associated varicosities as described later here. Three-percent STS was used for saphenous trunks because of its greater potency, and varying concentrations of polidocanol were used for visible varicosities to prevent phlebitis (lower concentrations of STS would be equally suitable). (3) Patients were required to walk immediately after treatment for 30 minutes and then 1 hour per day. All legs were placed in class 2, 30 to 40 mm Hg graduated compression hosiery for a minimum of 2 weeks after treatment (1 week of full time and 1 week during the day only). Avoidance of straining and strenuous physical activity was required for the first 3 weeks (to void Valsalva maneuvers, which may contribute to early recanalization). (4) Avoidance of prolonged car or plane travel of more than 4 hours for 1 month before and after treatment was required. (5) The end point of treatment was closure of incompetent saphenous trunks, incompetent branch veins, and all associated varicosities. Follow-up treatment was provided at 3 months if required. (6) A minimum of 1 year of follow-up since treatment was required.

Typical protocols for our patients include the following: (1) One leg: a treatment to the saphenous trunk (or trunks) involving typically four injections of 2-mL foam 3% STS with a repeat visit within 1 week to confirm closure of the saphenous trunk(s) and to treat the visible varicosities if not already closed. Typically, such follow-up treatments to visible varic-

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osities involve lower concentrations of sclerosant, for example, 0.5% to 2.5% polidocanol. Perforators—particularly Cockett perforators—will often need further treatment at the second visit, and this involves injecting at least 2 to 4 cm proximal or distal to the perforator, with concentrations varying dependent on the size of the perforator. (2) Two legs: The saphenous trunk(s) of one leg will be treated as previously mentioned, with the second leg being treated 2 days later and a third treatment to visible varicosities and/or distal perforators being completed 5 days later so that for the majority of patients the treatment of two legs is completed in three visits over 1 week with a follow-up at 3 months. We choose this protocol to minimize the time spent in compression hosiery. Duplex guidance is mandatory for the nonvisible components of the treated veins.

**Results**

One hundred legs were studied. Males represented 32%, and females represented 68% (an average of age 52). There were 55 left and 45 right legs. Eighty-nine legs had the greater saphenous vein treated, and 23 legs had the short saphenous vein treated, with 12 legs

having both greater and short saphenous veins treated. Seventy-three percent were CEAP class 2, 8% CEAP class 3, 18% CEAP class 4, and 1% CEAP class 6 (Figure 1).

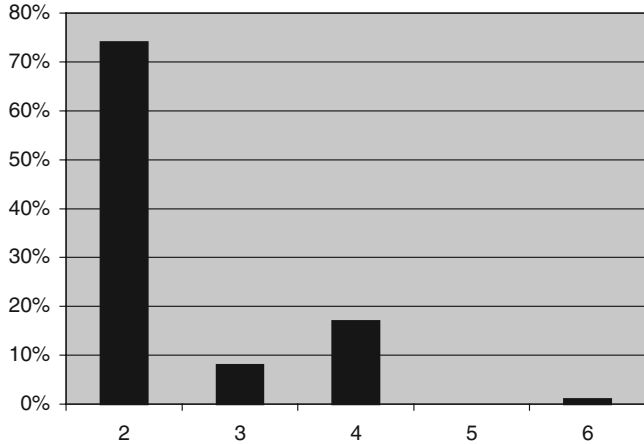
The average number of treatments required per leg, including saphenous trunks, branches, and all visible varicosities, was 2.19 (range of 1 to 5). Injection volumes at each session were 1 to 2 mL of foam (Figure 2).

The average total volume of STS 3% foam used for completion of all treatments totaled 8.7 mL (range of 2 to 25 mL) (Figure 3). Thirty-one percent of legs also required varying concentrations of polidocanol to visible varicosities dependent on size (5% polidocanol in 7% of legs, 2.5% polidocanol in 19% of legs, and 1% polidocanol in 5% of legs).

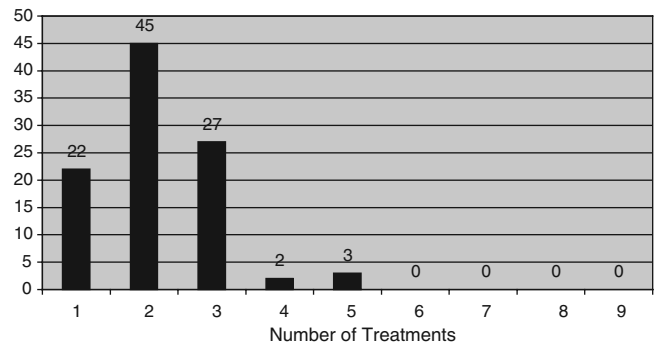
Thirty-one percent of legs required a second treatment at the 3-month follow-up (doses included in the previously mentioned totals). Such treatments were generally for a small channel in the saphenous trunk, a small feeding vessel or perforator creating the channel, or minor residual varicosities. Success of foam UGS was analyzed from two perspectives: patient satisfaction and clinical assessment.

*Patient Satisfaction*

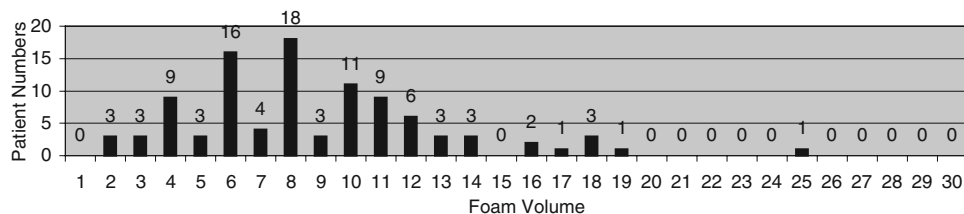
There was extremely high patient satisfaction. One hundred percent of patients felt that foam UGS had been successful for treating their varicose veins and their related symptoms. Eighty-five percent registered



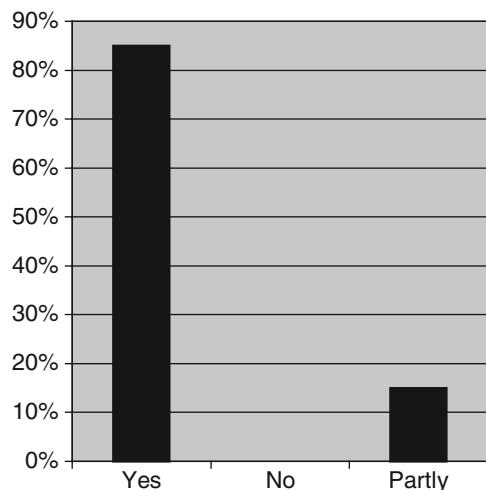
**Figure 1.** CEAP classification. Class 1: reticular and spider veins: excluded from study. Class 2: varicose veins. Class 3: varicose veins with edema. Class 4: varicose veins with skin changes (e.g., lipodermatosclerosis/varicose, eczema/atrophie blanche). Class 5: Varicose ulcers healed: none in study. Class 6: active varicose ulcers.



**Figure 2.** The average number of treatments.



**Figure 3.** Volume STS 3% foam.



**Figure 4.** UGS successes?

complete success, and 15% felt that foam UGS had been partly successful. For example, not all symptoms had completely resolved. Several patients with complete resolution of their varicosities and improvement in most symptoms still registered UGS as partly successful, as some of their symptoms had not resolved, for example, cramps. Nobody rated his or her treatment as a failure (Figure 4).

#### *Quality of Life Questionnaire*

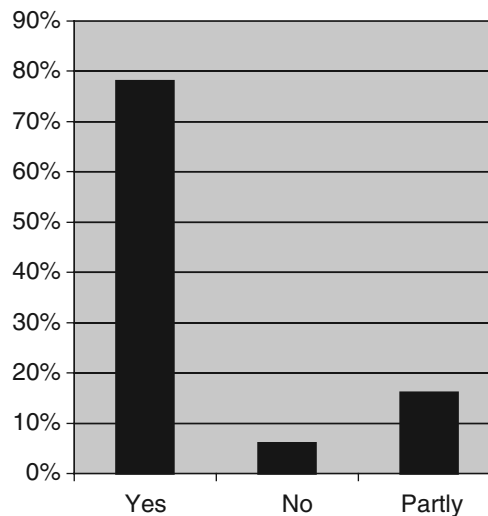
Ninety-four percent of patients felt that their quality of life had improved after treatment (78% complete and 16% partly). The balance did not have symptoms before treatment and did not register a removal of their varicose veins as an improvement in quality of life. One hundred percent of the patients felt that the appearance of their legs had improved since treatment (Figure 5).

#### *Clinical Outcomes of Foam UGS*

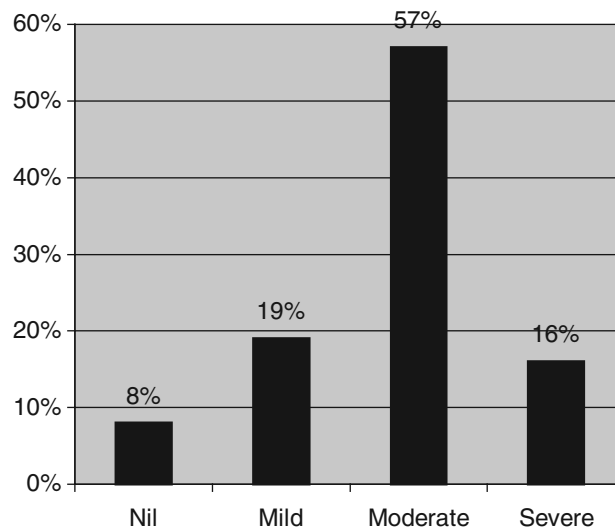
Ninety-two percent of legs had symptoms before treatment. The size of varicosities and the degree of reflux were not accurate predictors of symptoms (Figure 6).

After treatment, 86% showed improvement in symptoms (symptoms gone 38%, symptoms improved 48%). Fourteen percent showed no change, but the majority of the “no-change” group (57%) did not have symptoms before treatment (Figure 7).

Figure 8 demonstrates the percentage of patients with symptoms in each class before treatment (in black) and after treatment (in white). The difference reflects those patients who had shown either some



**Figure 5.** Quality of life improved?



**Figure 6.** Symptoms pretreatment.

improvement, much improvement, or symptoms that had completely gone.

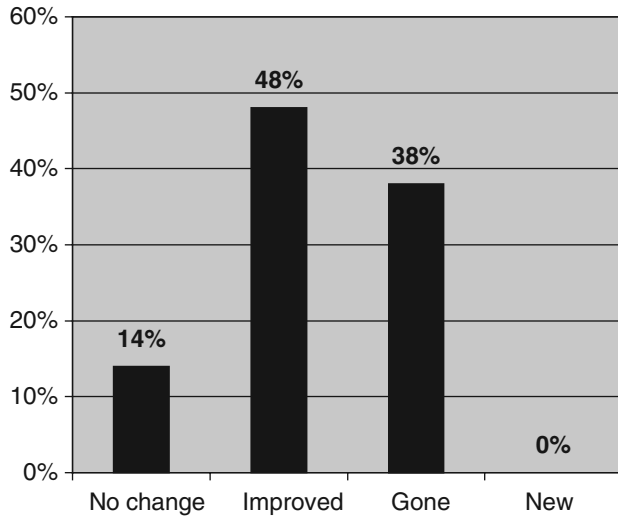
Table 1 shows a breakdown of the number of legs versus degree of improvement in each symptom group after treatment, culminating with the percentage improvement in each symptom group.

Symptoms in the “other” group included restless legs, heat, tenderness, bleeding, tingling, and superficial thrombophlebitis.

#### *Visible Varicosities*

One hundred percent of visible varicosities related to the treated saphenous veins were successfully treated clinically (92% completely removed, 8% significantly improved). Five percent had developed some minor

new varicosities related generally to perforator incompetence, and all were unrelated to the treated saphenous veins. These were minor and generally noted by doctor observation rather than pointed out by the patient (Figures 9 and 10A,B and 11A,B).



**Figure 7.** Symptoms posttreatment.

*Duplex Scan Assessment*

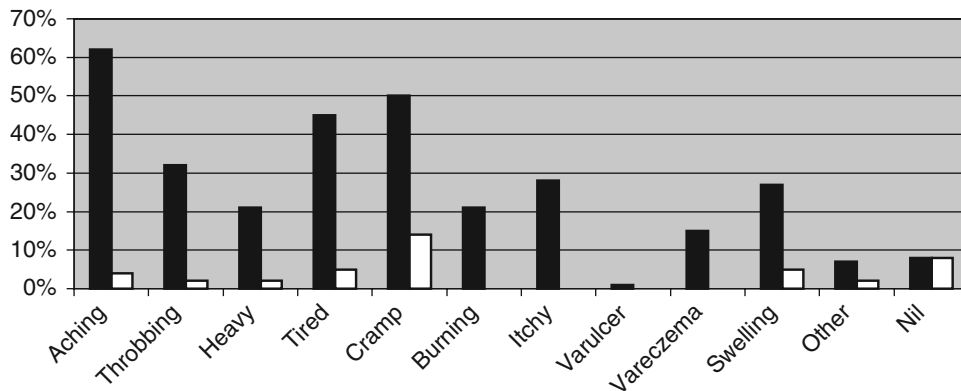
The mean follow-up interval was 22.5 months since the first treatment (range of 20 to 26 months). Twelve legs had both greater saphenous vein and short saphenous vein involvement, giving a total of 112 saphenous veins treated.

Duplex confirmed 97% successful treatment (86 saphenous veins complete sclerosis and 22 with fibrosed vein of less than 2 to 3 mm and minimal flow) of the saphenous veins. Four saphenous veins had reduced diameter but persistent reflux and would require further treatment if the varicosities returned; 11.6% (13 of 112) of the saphenous veins had a diameter at the junction of more than 10 mm. Results for this group were typically as good as for the 0- to 10-mm diameter group (Figure 12).

**Discussion**

Results achieved are comparable with other reports.<sup>1-4</sup> This study demonstrates high patient satisfaction with UGS combined with a high rate of closure of the saphenous trunks and visible varicosities.

There are a variety of established protocols for UGS with STS or polidocanol. There are two distinct



**Figure 8.** Symptoms pretreatment/posttreatment.

**Table 1.** Improvement by Symptom Class

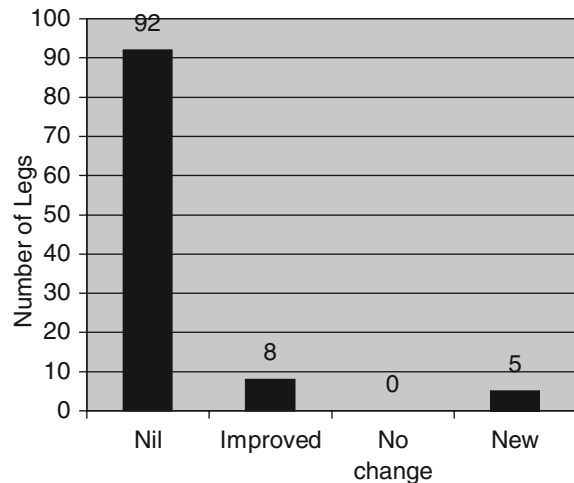
	Ache	Throbbing	Heavy	Tired	Cramp	Burning	Itchy	Varicose Ulcer	Varicose Eczema	Swelling	Other	Nil
Worse	0	0	0	0	2	0	0	0	0	0	1	0
No Change	4	2	2	5	12	0	0	0	0	4	1	8
Some Improvement	4	5	4	5	4	4	2	0	0	2	0	0
Much Improvement	23	10	3	12	15	6	10	1	8	9	0	0
No longer Occurs	31	15	12	22	17	11	18	0	7	10	3	0
Total Improved	58	30	19	39	36	21	30	1	15	21	3	8
Before Treatment	62	32	21	44	50	21	30	1	15	27	5	8
% Improved	93.6	93.8	95	88.6	72	100	100	100	100	70.4	60	0

approaches: low concentration/high volume and high concentration/low volume. The former group used concentrations of approximately 0.5% STS or polidocanol with volumes often in excess of 15 mL per treatment visit. The latter group used 3% STS or 5% polidocanol with lower volumes per treatment visit, typically less than 10 mL, with averages of approximately 6 to 8 mL. We have adopted the latter technique, as in our experience, the lower concentra-

tions tended to lead to more treatment sessions. Higher volumes inevitably lead to the deep venous system being exposed to more sclerosant. Although the effect of this is yet to be established, we have concerns that higher volumes may lead to an increase in thromboembolic events despite the weaker concentrations being used.

We believe the 3-month follow-up provides an optimal time to assess the development of early recanalization or the establishment of alternative venous pathways. We did not see an increase in recanalization after 3 months. Such potential causes of future recanalization can be dealt with at this time. There would be merit in also following patients at 1, 2, and 5 years; however, cost needs to be considered in such protocols. In our study of 100 legs, only 3% of legs at an average of 22.5 months of follow-up would have needed further treatment. There would be likely further improvements in closure efficiency with a 2-year follow up. It may, however, be more cost effective to wait until there are clinical recurrences or return of symptoms before offering further treatment rather than reviewing everyone at 1, 2, and 5 years.

There were no significant adverse reactions in the study. Intravascular coagulation (blood trapping) and hemosiderin staining are part of the healing process for a significant number of patients. The former typically



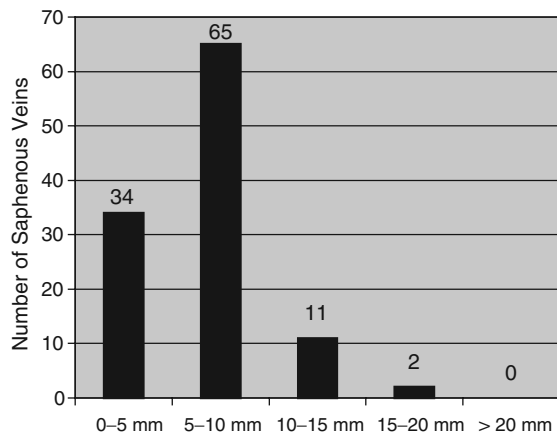
**Figure 9.** Visible varicosities posttreatment.



**Figure 10.** (A) Before UGS. (B) One week after UGS.



**Figure 11.** (A) Before UGS. (B) Three months after UGS.



**Figure 12.** Vein diameter pretreatment.

resolves over 3 to 4 months and the latter over 6 to 12 months. Telangiectatic matting did not occur in the study group.

Over the wider group of 2500 legs treated with foam UGS, we have had no serious adverse reactions (in particular, no episodes of thromboembolism or nerve injury). We have had three documented cases of minor deep vein thrombosis in the medial gastrocnemius vein with spontaneous resolution over 3 months. There have been no cases of allergic reaction to STS or polidocanol while using foam. We have noted four

cases of scotoma with or without migraine (in all cases mimicking the patients previous migrainous aura) and no cases of neurologic deficit. Matting was an issue in less than 1% of legs and was generally a sequel of excessive inflammation (as evidenced by local erythema and edema over an area of phlebitis confirmed by increased echogenicity surrounding the treated vein on Duplex scan). There have been no sclerosant-induced ulcers, no wound infections, and only two cases of neurasthenia (resolving within 6 months).

In conclusion, we believe foam UGS as described is a safe and effective treatment for all varicose veins. It can be used for all age groups, and the only medical contraindications include pregnancy, breast feeding, and allergy to both STS and polidocanol. A lack of mobility is a relative contraindication, as is significant deep-vein incompetence and a personal history of thrombophilia.

UGS is particularly useful for complicated post-surgical recurrences where there are multiple sources of recurrent reflux, including neovascularization and multiple perforators. Ultrasound guidance in real time and over serial treatments ensures closure of all relevant sources of reflux.

Given the efficacy of the technique, the added patient safety is a prime indication for UGS (no general anesthesia and immediate mobility reduces the risk of thromboembolism).

UGS has the added benefit of high patient satisfaction and relatively low cost. Treatment sessions last 20 to 30 minutes so that patients do not need significant time off work.

Endovenous laser treatment and VNUS closure by comparison require tumescent anesthesia and can only be used for relatively straight saphenous trunks. Treatment of the varicose veins typically requires additional treatment with ambulatory phlebectomy or sclerotherapy. Surgery carries a significantly higher risk of thromboembolism, wound infection, and nerve injury.

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