Ultrasound-guided foam sclerotherapy of great saphenous vein with 2% polidocanol – one-year follow-up results

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Abstract

Introduction: Ultrasound-guided foam sclerotherapy (UGFS) of varicose veins is a useful treatment option. It is a relatively safe method in the case of limited, small varicose veins. In theory, a justified concern could be raised that the injection of an active drug into the large superficial venous vessels may potentially cause life-threatening consequences.

Aim: To assess the safety and efficacy of UGFS using a 2% solution of polidocanol (Aethoxysklerol 2%) in the case of great saphenous vein incompetence.

Material and methods: Fifty-two patients with great saphenous vein incompetence underwent ultrasound-guided foam sclerotherapy. The efficacy criterion was the elimination of reflux measured ultrasonographically and withdrawal or decrease of complaints: 1 week, and 1, 3, 6 and 12 months after the treatment. Complications of sclerotherapy were reported during follow-up.

Results: Decrease or withdrawal of complaints of chronic venous insufficiency was reported in 96% of cases (50 patients). Disappearance or decrease of varicose veins was noted in all patients (100%). During examination after 12 months, full success of ultrasound was achieved in 38 (73%) cases, and 11 (21%) patients presented a partial desired effect according to the consensus from Tegernsee. Persistence of reflux longer than 1 s in the treated great saphenous vein was reported in 3 (6%) cases. Serious complications, such as deep vein thrombosis, pulmonary embolism, dyspnea, anaphylaxis, or neurological abnormalities, were not recorded.

Conclusions: Ultrasound-guided foam sclerotherapy of incompetent great saphenous vein and varicosities with 2% polidocanol was found to be an effective and safe method of treatment during 1 year of observation. However, longer observation is necessary.

Key words: varicose veins, Doppler ultrasound, foam sclerotherapy, ultrasound-guided sclerotherapy, polidocanol.

Introduction

Varicose veins are often associated with great or small saphenous veins reflux and affect approximately one third of adults in the western world [1]. For many years stripping of the saphenous vein with varicectomies has been a standard treatment. However, the operation is a traumatic experience for patients. Surgical treatment may also be associat-

ed with serious complications such bleeding, groin infection, thrombophlebitis, saphenous nerve injury or even life-threatening conditions [2]. Additionally, recovery after the operation is quite long. General or regional anesthesia during a conventional operation increases the costs of treatment [3].

In recent years many less aggressive methods of endovenous treatments of varicose veins, such as sclerotherapy, thermoablation (radiofrequency, laser,

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steam ablation) and intravascular glue have been introduced. In the majority of countries these methods are not reimbursed and the costs play an important role in their use. The least invasive, among mentioned ways of treatment, is foam and/or liquid sclerotherapy.

The first person who used foam sclerosant was Orbach in 1944 [4]. Cabrera *et al.* in 1997 performed ultrasound-guided sclerotherapy [5]. Finally Tessari introduced the newest method of producing a foamy sclerosant in 2000. He used two syringes and a three-way tap [6]. This method gave the opportunity to achieve stable foam consisting of small bubbles.

Material and methods

Fifty-two patients with great saphenous vein incompetence underwent ultrasound-guided foam sclerotherapy (between 2008 and 2010). The treatment was performed only from October to March of each year (2008/2009 and 2009/2010). All patients

were informed about the chronic venous disease and the methods of treatment. They were also informed about the ultrasound-guided foam sclerotherapy, indications and contraindications as well as possible complications and gave their informed, written consent to the procedure.

Aethoxysklerol 2% has been approved for vein sclerotherapy in Poland. Its use does not require approval of the institutional review board.

Before drug injection the medical history was taken. Patients were then physically examined. All of them had a normal pulse on lower limbs and no signs of peripheral artery disease. Inclusion and exclusion criteria are shown in Table I. Treated lower limbs were classified according to the CEAP system [7]. Duplex ultrasound of the lower extremity was a standard modality performed before each treatment by the same operator. After clinical and ultrasound examination legs were classified as follows: In clinical classification varicose veins with or without edema and/or pigmentation or eczema (C2, C3,

Table I. Inclusion and exclusion criteria [7]

Inclusion criteria	Exclusion criteria	
Patients with thigh GSV incompetence with or without of SFJ reflux; with or without incompetence below the knee	Patients without GSV incompetence	
Diameter of the GSV below SFJ between 4 and 10 mm – measured in standing position	The GSV diameter less than 4 and larger than 10 mm	
Age between 18 and 65 years	Minors and patients older than 65 years	
Patients agreeing to take part in the treatment and having given written informed consent	Patients who did not sign the consent	
CEAP classification: C2 to C4a, Ep, As with or without Ap, Pr	CEAP classification: C0, C1, C4b, C5, C6.Ec, Es. Ad. Po, Pr,o	
No signs of serious respiratory, circulatory or digestive system diseases	Psychiatric disorders present at the time of treatment	
No signs of peripheral artery diseases	Chronic renal disease	
	Chronic liver disease	
	Pregnant or breastfeeding women	
	Known malignant disease	
	Known coagulopathy	
	History of deep vein thrombosis	
	Allergy to polidocanol	
	Intolerance of alcohol	
	Known PFO or ASD	

GSV – great saphenous vein, SFJ – sapheno-femoral junction, CEAP – Clinical – Etiology – Anatomy – Pathophysiology, PFO – patent foramen ovale, ASD – atrial septal defect.

C4a), in etiologic classification alterations were primal (Ep), in anatomic classification superficial with or without perforators (As,p), and in pathophysiologic classification only reflux was observed (Pr).

Before treatment and during follow-up photographic documentation was made. It was intended to assist in further assessments of the results and effects of the method. Patient examination, foam production and the procedure of drug administration were performed according to the consensus on foam sclerotherapy from the 2nd European Meeting on Foam Sclerotherapy in Tegernsee [8].

Ultrasound evaluation was performed in the standing position using a 5–9 MHz linear transducer. Blood flow was elicited with manual compression and release below the transducer. Incompetence was diagnosed if reflux lasted longer than 0.5 s.

Foam production

Foam was produced manually using two connected sterile disposable syringes. One syringe contained 2 ml of 2% polidocanol (Lauromacrogolum 40; Aethoxysklerol 1%, Kreussler Pharma, Germany) and the second contained 8 ml of air. Foam was obtained by mixing together drug and air in a ratio 1:4.

Treatment

During the intervention patients lay in the supine position. The treated leg was gently elevated. Before drug injection the intravenous cannula was introduced into the great saphenous vein (GSV) about 10-15 cm below the sapheno-femoral junction (SFJ) and in 5 cases additionally below the knee level. In these 5 cases GSV was incompetent on the thigh and partially on the distal half of the calf. The amount of foamy sclerosant never exceeded 10 ml (average 7 ml). During drug administration the SFJ area was compressed with a transducer or specially prepared wadding roller. As the injection was finished, the great saphenous vein was checked on US to prove that foam filled the vein completely and no propagation to deep veins (common femoral vein, femoral vein and veins below the knee) was present. Elastic compression (class II compression stockings - from 20 to 30 mm Hg) was applied by the doctor performing sclerotherapy after the treatment and the groin compression was slowly released. Patients were encouraged to wear the compression stockings during the first 48 h (day and night). Then the stockings were advised for a further 12 months only during daytime activity. Six months after sclero-therapy the compression was changed to class I (between 10 and 20 mm Hg).

In the assessment of results the efficacy criteria were as follows: elimination of reflux in the treated vein and withdrawal or decrease of complaints during follow-up. Patients were followed up 1 week, and 1, 3, 6 and 12 months after the treatment. Complications of sclerotherapy were reported during follow-up.

Clinical effects were assessed regarding patients' complaints and the state of varicose veins after treatment. The clinical assessment was divided into three grades:

- 2 normalization lack of visible varicose veins;
- 1 improvement smaller visible varicose veins;
- 0 lack of improvement or worsening of clinical state according to the CEAP classification.

The ultrasound assessment was also divided into 3 grades:

- 2 full success lack of reflux;
 - 2a totally obliterated vein;
 - 2b totally occluded (incompressible) vein;
 - 2c presence of an unobliterated vein, with reduced diameter (compared to the pre-treatment assessment) and no reflux;
- 1 partial success reflux less than 1 s or partial incompressibility or partial obliteration of treated vein with decrease of its diameter;
- 0 failure of treatment reflux longer than 1 s or without any changes compared to the pre-treatment time; total or partial persistence of vein diameter and/or without its change compared to the pre-treatment state.

Results

From October 2008 to March 2009 and from October 2009 to March 2010, 52 patients with GSV incompetence and with or without concomitant varicose veins were treated with sclerotherapy. There were 46 (88.5%) female and 6 (11.5%) male patients in the group. Mean age was 54 (from 30 to 65) years.

Decrease or withdrawal of complaints of chronic venous insufficiency was reported in 96% of cases (50 patients). Disappearance of varicose veins or their decrease was present in all patients (100%). Full success (grade 2) of ultrasound was achieved in 38 (73%) cases, and 11 (21%) patients presented a partial desired effect (grade 1), a year after the

treatment. Persistence of reflux longer than 1 s in the treated GSV was observed in 3 cases (6%).

One-week follow-up

During the first visit, a week after the treatment, patients were examined to exclude asymptomatic deep vein thrombosis (DVT) and to check desired occlusion of the vein. Ultrasound examination revealed no signs of DVT. Additionally all patients had a correctly occluded GSV (Photos 1 A, B).

1 month after treatment

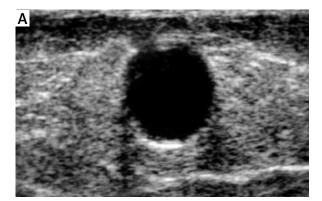
At 1 month after sclerotherapy patients were checked for thrombophlebitis and/or need for evacuation of the clot. During this visit occlusion of the treated vessel was evaluated (Photos 2 A, B).

3, 6 and 12 months after sclerotherapy

Patients were physically examined and US of treated vein was performed. During these examinations

the clinical effects and vessel occlusion were assessed according to the consensus on foam sclerotherapy from the 2nd European meeting in Tegernsee [8].

Patients were asked about their complaints and impressions. Follow-up examinations revealed that while using compression stockings complaints were at least smaller. All (100%) patients reported improvement during the first 3 months of follow-up. It was the period of wearing the stockings. A few patients decided to guit compression after this time, but returned to the treatment when symptoms increased again. Only 2 (4%) persons did not return to compression stockings despite symptoms of chronic venous insufficiency. These patients claimed they could not tolerate the compression even despite the change of the compression to class I. Obviously they did not report the decrease of severity of symptoms. Before sclerotherapy they suffered from mild to moderate pain of the treated leg. Most persons (50, 96%) noticed improvement and the decrease or withdrawal of complaints.



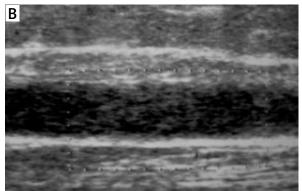
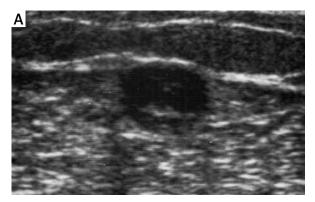


Photo 1 A, B. Great saphenous vein a week after sclerotherapy in transverse and longitudinal projections; blood flow is not present



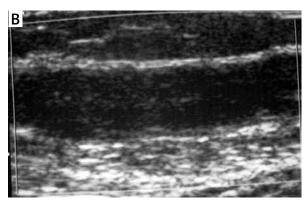


Photo 2 A, B. Great saphenous vein 1 month after therapy. Total occlusion of the vessels without any signs of revascularization

Table II. Results of ultrasound examination of GSV during follow-up visits 3, 6 and 12 months after the treatment

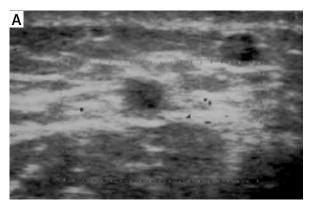
Follow-up visits [months]	Grade 0 (reflux > 1 s or unchanged)	Grade 1 (reflux < 1 s)	Grade 2 (no reflux)
3	2 (4%)	3 (6%)	47 (90%)
6	3 (6%)	9 (17%)	40 (77%)
12	3 (6%)	11 (21%)	38 (73%)

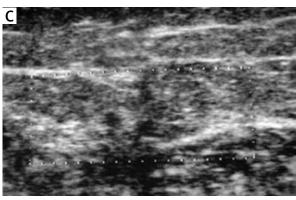
Patients' physical examination, during 1-year follow up, revealed disappearance (grade 2) or decrease of varicose veins (grade 1) in all cases (100%). Therefore all patients reported normalization or at least improvement of clinical state.

Table II present results of ultrasound examination 3 and 6 months and 1 year after the treatment. A 1-year follow-up visit revealed grade 2 in 38 cases (73%) and grade 1 in 11 cases (21%). Failure in US was recorded in 3 (6%) patients. Therefore full or partial US success was achieved in 94%. Photos 3 A—C present the correctly occluded GSV without any signs of blood flow respectively after 3, 6 and 12 months.

Complications

Six (11.5%) patients felt moderate pain at the site of injection as it was administered. A week and a month after sclerotherapy thrombophlebitis of part of the treated vein or its tributaries was present in 11 (21%) cases. The thrombus was evacuated by vein puncture or small incision a month after treatment. During further follow-up, hyperpigmentation, fading with time, was observed on the skin of the thigh or calf in 9 (17%) cases. This complication was not present along all the vein. After 1 year pigmentation was hardly visible in 8 (15%) cases and 1 patient had clearly visible hyperpigmentation on the calf





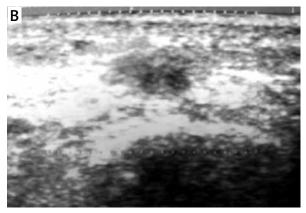


Photo 3 A–C. Great saphenous vein during follow-up 3, 6 and 12 months after therapy. The treated vein fully obliterated without any signs of patency in US



Photo 4. Hyperpigmentation 3 months after GSV foam sclerotherapy. Patient did not use compression stockings properly

(2%) (Photo 4). This patient did not wear the stocking correctly (all day) through the first 3 weeks after the treatment. Finally she decided to cease using the stocking after 3 months of follow-up, claiming that it was not possible to tolerate the compression, especially in warm seasons. Interestingly, this person had a partially occluded treated vein with reduced diameter in the ultrasound examination after 1 year.

In the cases of hyperpigmentation on the thigh the GSV was located no deeper than 1 cm under the skin. Moreover, patients with the complication on the calf did not use compression stockings properly.

Serious complications such as DVT, pulmonary embolism (PE), dyspnea, anaphylaxis or neurological abnormalities (vision disorders, vertigo and loss of consciousness, stroke or transient ischemic attacks) were not recorded. Additionally, the complication of too strong compression after the treatment was reported in 5 (10%) cases. After sclerotherapy the limb was compressed with the stocking and additionally with an elastic bandage. Due to too strong bandaging 5 patients reported tingling and numbness of the toes. During a telephone call they were told to remove the bandage, which eased the symptoms.

Discussion

Chronic venous insufficiency is a very common problem in Poland. Surgical treatment is still the main procedure at every level of the disease above the clinical state C1. Surgical treatment has never been considered necessary for telangiectasias. There is a wide armamentarium of therapeutic op-

tions in more advanced clinical states of venous insufficiency.

The choice of the best approach depends on many factors: stage of the venous lesion according to the CEAP classification, location of this lesion, cost of the treatment, complaints, concomitant diseases and obesity, willingness to resume work, prejudice against some methods of treatment or their complications, etc. Some of these factors, e.g. cost of treatment and willingness to work, may be related to specific economic conditions in Poland.

There are not many investigations comparing different methods of treatments of venous disease in our country. However, it can be suspected that the comparison may be similar to those performed in other counties. Rasmussen et al. from Denmark proved that stripping of GSV is as expensive as endovenous laser ablation (EVLA). The time to resume work and normal activity was the longest after surgery compared to EVLA, radiofrequency ablation (RFA) and ultrasound guided foam sclerotherapy (UGFS). The RFA was shown to be a little less expensive than EVLA with a similar rate of complications except thrombophlebitis. Ultrasound-guided foam sclerotherapy was the cheapest and the most convenient method of treatment of incompetent GSV and varicose veins. However, it was noted that UGFS had the highest rate of patency one year after treatment [3]. During the Second European Meeting on Foam Sclerotherapy in Tegernsee in 2006 the majority of experts recognized the necessity of compression after intravenous foam administration. However, it was not formulated as a consensus [8].

Searching for the perfect treatment one should consider that the method should be the most convenient. It should also be related to the lowest complication rate, the lowest recurrence rate, the highest clinical success rate and the lowest cost possible [9]. The problem is that such a method does not exist. We are obliged to choose the best treatment for each patient considering the severity of the disease, his or her expectations, willingness for cooperation after treatment and the costs. Patients should always be informed about the recurrence of varicose veins and GSV incompetence.

All methods of treatment have their advantages and disadvantages. One disadvantage is recurrence. Widespread surgical treatment, despite its well-known benefits, has a recurrence rate which ranges from 25% to above 50% at 5-year follow-up [10–13]. This recurrence does not have to be linked

with a particular method of treatment but may simply derive from the nature of the disease.

Rasmussen *et al.* in their investigation comparing UGFS, radiofrequency ablation (RFA), endovenous laser ablation (EVLA) and surgery reported the highest recurrence of reflux in treated GSVs 1 year after foam sclerotherapy. These authors however recognized this method as the least traumatic, the cheapest and easy to repeat [3]. The treatment itself is relatively easy to perform, effortless and can be conducted in an outpatient clinic [14]. The above conclusions were accepted in our practice. The places of insertion of the intravenous catheter, amount of foam and its production and drug concentration were in accordance with the Consensus from the 2nd Meeting on Foam Sclerotherapy [8].

As stated previously, sclerotherapy has advantages and disadvantages. Among the latter the most important are recurrence rate, risk of DVT, thrombophlebitis and related hyperpigmentation.

There are some methods which may potentially decrease the risk of negative consequences of the therapy.

During foam administration the area of the sapheno-femoral junction was compressed. However, in the literature some authors consider that such compression has no impact on the results and is simply not necessary [15]. After the intervention the stockings and additional elastic bandage were worn. This practice is recommended by most experts. Yet it is not a part of the consensus [8]. Also the duration of initial stockings use is not clearly described. In our practice the compression was left without change for approximately 48 h. Such duration of initial compression is also recommended by Rasmussen *et al.* and Alos *et al.* [3, 16]. Others recommended longer initial compression, lasting even 2 weeks [14].

To assess the vein occlusion, and diagnose and manage the complications of the treatment it is important to follow each patient properly. The aims of follow-up visits should not be limited to gathering knowledge. Continuous care for patients should be the priority. Follow-up examinations were planned to assess the efficacy of the therapy and to apply the proper management in case of failure or complications. That is why patients were followed up at 1 week, and 1, 3, 6 and 12 months after the treatment. Similar follow-up has also been suggested by other authors [14–17].

The decision about thrombus evacuation, in the case of thrombophlebitis of the GSV or its tributaries, was taken 1 month after treatment. Thrombectomy was performed through a small incision or puncture of the vein. Similar practice was proposed by Hamel-Desnos *et al.* and Coleridge Smith [14, 18].

An ultrasound examination performed a week after therapy proved correct obliteration of the treated vein in 100% of cases and additionally did not reveal signs of DVT. Thus no resclerotherapy was necessary. Obtained results 1 week after sclerotherapy are similar to those reported previously by others [3, 18].

Further follow-up examinations proved satisfactory efficacy of ultrasound-guided foam sclerotherapy. Results in the literature differ according to drug concentration, way of drug administration, used compression and assessments.

Rabe *et al.* reported occlusion of GSV 3 months after treatment in 70% of cases [19], whereas Bountouroglou *et al.* noted success in 87% [9]. Both authors used 3% foamy polidocanol for sclerotherapy.

According to Gonzalez-Zeh *et al.* and Figueiredo *et al.*, patent GSV 6 months after sclerotherapy was observed in 11.3% and 22% respectively [20, 21].

In the literature, the success rate, defined as occlusion of the GSV, at 1 year after sclerotherapy, ranges from 77.4% to 88% [3, 14, 20]. Our results despite different concentration of the drug and prolonged compression therapy up to 1 year are similar to those obtained by other authors.

The vast majority of authors used 1% or 3% foamy sclerosant. Only Hamel-Desnos *et al.* performed sclerotherapy with 1% and 2% drug concentrations. But their investigation needs to be continued due to too short observation – 28 days [18].

The most frequent complication after sclerotherapy was thrombophlebitis in our material. It was present in 11 (21%) cases and was never recorded along all the great saphenous vein. The rate of this complication in the literature is not so frequent. Many authors have reported phlebitis with frequency ranging from 2% to 10% [14, 18, 22]. Only Gonzalez-Zeh *et al.* and Figueiredo *et al.* reported approximately 42% and 74% rates of the complication respectively [20, 21]. These results obtained by Figueiredo *et al.* may derive from different criterion of thrombophlebitis diagnosis. Also, compression that is initially inadequate could be another cause of increased rate of thrombophlebitis. Some authors

claim that more concentrated sclerosants can also increase the frequency of phlebitis [23].

Thrombophlebitis and maybe its incorrect evacuation can increase the frequency of hyperpigmentation. The rate of this complication ranges from 2% to 25% and depends on time [14, 22]. In our investigation the frequency of hyperpigmentation was 17% (9 patients) at 1 month after the drug administration. It faded with time and during 1 year after the intervention it was only observed in 15% (8 patients). Our results are slightly worse than those presented by others, but it may be due to the different method of assessment, conditions during assessments and different shades of skin.

There are some methods potentially decreasing the frequency of the complication and improving the fading. Thrombus evacuation is one of the most important. It can be performed by vein puncture or incision. In practice one tries to match the proper method and thrombus size. Additionally, none of these methods have been assessed regarding their efficacy.

Very interesting practice was proposed by Abela *et al.*, who asked patients for postsclerotherapy bruising assessment. Interestingly, the patients' own assessment of their legs was worse than the assessment by observers. This may also suggest that other complications could look worse in patients' subjective evaluation [24].

Conclusions

Ultrasound-guided foam sclerotherapy with 2% polidocanol can be a good method for management of incompetent great saphenous vein. It cannot be regarded as a perfect therapy for everybody at every level of the disease. Only a well-constructed randomized, prospective and standardized investigation performed on numerous groups of patients can give us answers about the efficacy and safety of the foam sclerotherapy using a 2% solution of polidocanol.

Conflict of interest

The authors declare no conflict of interest.

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