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ORIGINAL ARTICLE

Association of greater saphenous vein diameter and clinical severity score after treatment of severe chronic venous insufficiency with foam sclerotherapy

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KEYWORDS

Saphenous vein
Sclerotherapy
Varicose ulcer
Venous insufficiency

ABSTRACT

Objective: to evaluate the association of the greater saphenous vein (GSV) diameter in the treatment of patients with severe chronic venous insufficiency (C6 CEAP classification) with ultrasound-guided polidocanol foam sclerotherapy (UGFS).
Methods: A prospective, descriptive, and analytical study of 28 patients (30 limbs) that underwent UGFS. Patients were divided into 2 subgroups by GSV diameter (< 8 mm and ≥ 8 mm). Variables analyzed were ulcer healing, clinical intercurrences, clinical CEAP classification, Venous Clinical Severity Score (VCSS), diameter of the treated vein and presence of occlusion or recanalization by Doppler ultrasound. Patients were analyzed at the 1st, 3rd, and 6th months post-treatment.
Results: The average age was 68.7 ± 10.5 years, 23 (82,1%) were women, and the average body mass index was 29.2 kg/m^2. Although an improvement in VCSS score was observed during follow-up, no significant intergroup difference was noted. Seventeen (56%) limbs presented occlusion of the treated vein at the 1st month, 11 (36%) at the 3rd month, and 9 (30%) at the 6th month of follow-up. The ulcer healing rate was 56,6%. The average ulcer healing time was 90 days. Three (10%) patients presented with ulcer recurrence at the 6th month. Survival analysis showed no significant difference in ulcer healing rate between subgroups after one year of follow-up (log-rank, p = 0,178).
Conclusion: There was no difference between the subgroups of large and small VSM diameter in terms of symptom severity. However, significant reduction of VCSS and pain relief was observed after foam sclerotherapy.

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INTRODUCTION

Chronic venous insufficiency (CVI) of the lower limbs is characterized by signs and symptoms resulting from venous hypertension, commonly caused by reflux due to valve insufficiency[1]. CVI clinically manifests with varicose veins, pain, edema, perimaleolar hyperpigmentation, eczema, lipodermatosclerosis, and venous ulcers[2,3]. CVI is a common condition that significantly impacts patients' health and quality of life[3,4]. Venous ulcers are present in the more severe disease stages, with a prevalence estimated at 2% of the adult population, and they exhibit slow healing processes and high recurrence rates[5].

Treatment modalities for CVIs aim to improve symptoms, prevent complications and, when present, heal the ulcer. Compression therapy, conventional surgical procedures, and other minimally invasive procedures, such as intravenous laser ablation, radiofrequency ablation, and foam sclerotherapy, are used[5].

Foam sclerotherapy is a technique that consists of the injection of an irritating substance (sodium tetradecyl sulfate or polidocanol) mixed with some gas into the vascular endothelium of the incompetent vein, where an inflammatory response is triggered, resulting in localized thrombosis and sclerosis of the vessel[6]. The procedure has easy execution, the possibility of repetition, a quick recovery time, and a low cost; it does not require anesthesia and is associated with a low rate of adverse effects[7-9].

The technique used to produce foam in sclerotherapy is based on Tessari et al.[10], with a mixture of air and the sclerosing liquid injected into the intravascular medium through a percutaneous puncture guided by ultrasound[11,12]. Some foams are made manually just before the injection, called "homemade foam", with variations due to different preparation techniques and physicochemical characteristics of the sclerosing agent. In contrast, others are ready-made (for example, the intravenous polidocanol microfoam Varithena™, marketed in the United States). These foams have differences concerning their stability and cohesiveness, but the evidence is limited about the occurrence of embolic phenomena and their relative effectiveness[13,14].

Previous studies have demonstrated similar efficacy of sclerotherapy in improving venous symptoms, quality of life, and healing ulcers as other treatment modalities, despite higher rates of recanalization and reflux during long-term follow-up[8,12,15-18]. Currently, the following factors are associated with higher rates of reflux recurrence after two years of sclerotherapy: greater saphenous vein (GSV) diameters greater than 6 mm and GSV distal reflux[19,20]. Additionally, larger GSV diameters also correlated with higher CEAP classifications, venous symptoms, and proximal reflux[21]. However, few studies have addressed the treatment of incompetent GSVs with large diameters. Shaidakow et al.[22] and Woo et al.[23] analyzed groups with GSVs above 14 mm and 12 mm, respectively, and observed satisfactory radiofrequency ablation results.

The Venous Clinical Severity Score (VCSS) stands out among the clinical severity classifications because it aggregates CVI-related signs and symptoms and can be used as a clinical improvement parameter even after treatment[24,25]. There is no report of the use of the VCSS as a method for measuring clinical improvement in patients with venous ulcers and large diameters of GSV undergoing foam sclerotherapy. Therefore, this study verified the association of the GSV diameter in patients with severe CVI (CEAP C6) and ultrasound-guided foam sclerotherapy (UGFS) with the evolution of the clinical severity score VCSS 6 months after treatment.

METHODS

This is a descriptive, prospective study of patients with CEAP C6 CVI undergoing UGFS with polidocanol at the vascular surgery division of Itajubá Clinics Hospital (HCI), from December 2017 to January 2020. The following inclusion criteria were considered: 18 to 90 years old, patients with active venous ulcers, and patients who underwent UGFS. Pregnant patients with a history of recent deep venous thrombosis, peripheral arterial insufficiency with ankle-brachial index < 0.8, a diagnosis of thrombophilia, allergy to polidocanol, bronchial asthma, or diabetic foot were excluded.

The vascular surgery team evaluated the patients, and their clinical history and physical examination results were recorded with a description of their clinical characteristics, CEAP classification, and VCSS[24,25]. The following characteristics of the patients were registered: age, sex, number of pregnancies, body mass index (BMI), smoking, physical inactivity, prolonged work in the orthostatic position, family history of CVI, history of saphenectomy, limb affected by CVI, previous episodes of venous thrombosis and phlebitis. Before treatment, the following ultrasound information was recorded: deep venous system, GSV, small saphenous vein (SSV), perforator reflux, diameters of the treated superficial veins, and patency or incompetence of the deep venous system.

Patients were divided into two subgroups according to the pretreatment GSV diameter, and the cutoff point was defined as 8 mm. The following variables were analyzed at each return visit after foam sclerotherapy: ulcer healing, complications caused by treatment, CEAP classification, VCSS (with parameters scored 0–3: pain, varicose veins, venous edema, pigmentation, inflammation, induration, use of compressive therapy, number of active ulcers, duration, and size of the ulcer)[25], the diameter of the treated vein and the presence of occlusion or venous recanalization. Patients returned after 7 days, 1, 3, and 6 months for reassessment. However, all patients were followed up without a projection of discharge to assess the evolution of the lesions. A qualified professional performed a venous ultrasound at each return visit, where the permanence of the occlusion or recanalization and the diameter of the treated veins were analyzed. The occurrence of adverse reactions was also recorded at each return.

Foam sclerotherapy was performed outpatient, and the puncture was guided by Doppler ultrasound. The GSV and SSV (as defined in a previous examination) were punctured with an 18 G Jelco™ or 21 G or 23 G butterfly needle, according to the required depth. The foam was prepared with a mixture of 2 mL of 3% polidocanol and 6 mL of ambient air, performed with the aid of a three-way stopcock connected to two 10 mL syringes, similar to the technique of Tessari et al.[10,12]. After treatment, all patients received drug thromboprophylaxis with rivaroxaban 10 mg/day for a period of 7 to 30 days,

according to risk scores for venous thromboembolism. All patients maintained elastomer pressure during the morning and afternoon periods in the post-procedure follow-up period.

The ulcer healing survival curves were calculated from the date of the first treatment session until the end of the proposed follow-up.

The variables were subjected to descriptive statistics with the mean, standard deviation, absolute or relative frequency. For the analysis of the pre- and posttreatment VCSS values compared to the saphenofemoral junction (SFJ) diameters, a t-test for independent samples was used, while the Kruskal-Wallis test analyzed the evolution of the VCSS during the follow-up, both considering α = 0.05. The Kaplan-Meier survival curve was used to analyze ulcer healing time, and the long-rank test compared curves between groups. GraphPad Prism v.9 software (San Diego, CA, USA) was used.

This study was approved by the Ethics and Research Committee of the Faculty of Medicine of Itajubá (CAAE: 79577917.6.0000.5559, decision nr. 2,384,578) and followed the principles of the Declaration of Helsinki and Resolution 466/2016 CNS/MS/BR regarding ethical principles of conducting medical research in human subjects. All participants signed an Informed Consent Form.

RESULTS

Twenty-eight CEAP C6 patients (thirty venous leg ulcers) were selected from among 40 patients considered eligible for foam sclerotherapy from December 2017 to January 2020. Of these, 20 were followed up at one month of treatment, and only 13 after 6 months, representing a loss of 54%. There were fewer patients in the follow-ups due to returns outside the stipulated period or insufficient data, especially a lack of Doppler ultrasound information.

Among the participants, 23 (82.1%) were women. The average age was 68.7 ± 10.5 years, and the average body mass index (BMI) was 29.2 kg/m^2. The most frequent comorbidity was systemic arterial hypertension, present in 19 (67.9%) patients, followed by diabetes mellitus in 2 (7.1%) and heart disease in another 2 (7.1%) patients.

The number of sclerotherapy sessions varied from 1 to 4 (average 1.6 sessions/patient). Among these 28 patients, two had bilateral CVIs and underwent treatment on both limbs, while the remainder had only one limb treated. A total of 30 lower limbs were treated: 16/53.3% on the right side and 14/46.7% on the left. Furthermore, 20 GSVs were treated alone, and 8 SSV were treated together with GSV. Thirteen participants had associated deep venous system reflux.

Patients with active venous ulcers had an average ulcer duration of 96 months before treatment, with a minimum of 2 and a maximum of 480 months.

GSV, VCSS, and VCSS pain values

Table 1 shows the evolution of the diameters of the GSV, VCSS, and the isolated VCSS pain values in the sample from pretreatment to 6 months of follow-up. It was possible to observe a statistically significant decrease in values over time. Table 2 and Figure 1 show the analysis of the VCSS values for patients in the groups with SFJ < 8 mm and SFJ ≥ 8 mm over the study period. It was impossible to observe a statistically significant difference in the VCSS values concerning the SFJ size, regardless of follow-up time.

Table 1 — Values of saphenofemoral junction, VCSS and isolated VCSS pain score in the sample analyzed during the follow-up period. Values are average ± standard deviation.

Parameter	Time				p-value *
	Pre	1 month	3 months	6 months	
JSF (mm)	9.3 ± 3.7	7.1 ± 3.9	6.5 ± 2.8	5.6 ± 1.6	0.0005
VCSS pain	2.1 ± 1.0	1.1 ± 1.1	0.6 ± 0.8	0.5 ± 0.7	< 0.0001
VCSS	20.0 ± 3.4	14.1 ± 5.6	11.3 ± 6.1	10.1 ± 6.9	< 0.0001

*Kruskal-Wallis test

Table 2 — VCSS values during the follow-up period according to the size of the saphenofemoral junction (< 8 mm and ≥ 8 mm).

Time	VCSS - mean ± SD		p-value *
	JSF < 8 mm	JSF ≥ 8 mm	
Pre	19.5 ± 3.5 (n = 13)	20.4 ± 3.4 (n = 17)	0.48
1 month	15.9 ± 5.8 (n = 14)	13.8 ± 5.1 (n = 12)	0.36
3 months	12.4 ± 7.3 (n = 5)	10.4 ± 5.6 (n = 7)	0.60
6 months	10.3 ± 4.3 (n = 7)	11.5 ± 8.2 (n = 6)	0.73

*t-test for independent samples.

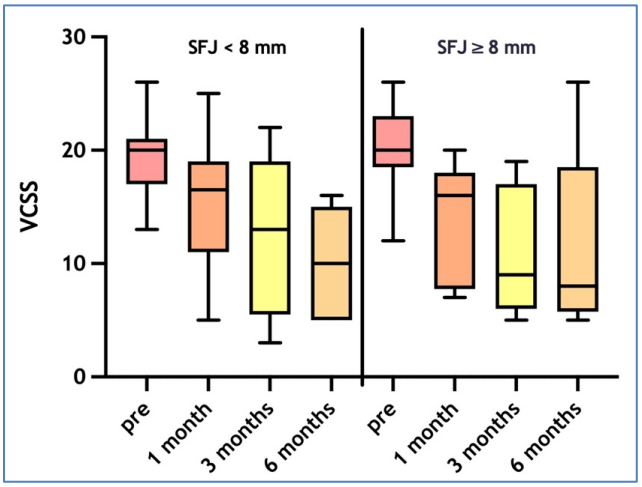

Figure 1 — Evolution of Venous Clinical Severity Score (VCSS) values over the follow-up time, according to the initial diameter of the saphenous-femoral junction (SFJ).

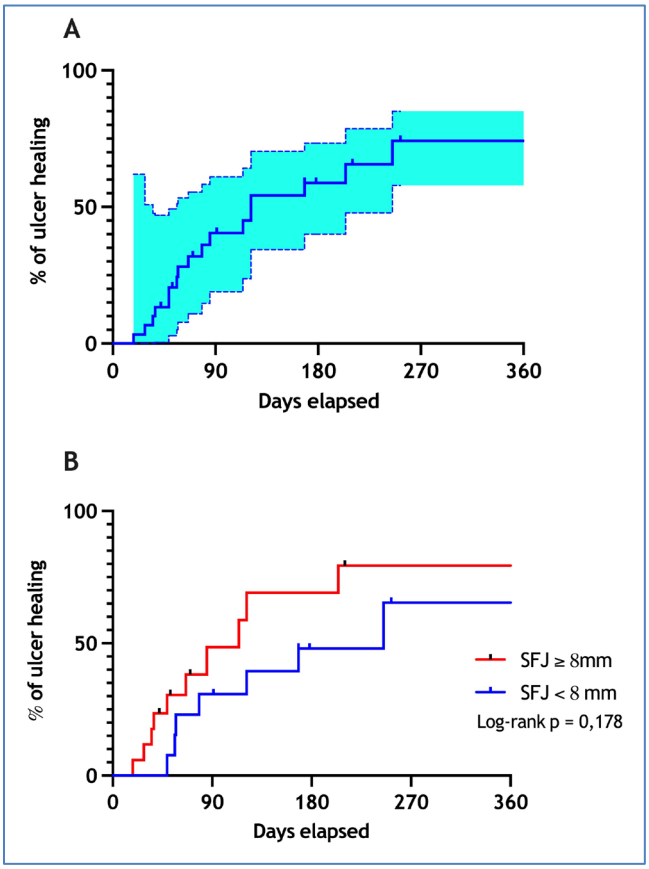

Figure 2 — Kaplan-Meier curves for ulcer healing during one year of follow-up. A, ulcer healing proportions for all 30 treated limbs, with 95% confidence interval (cyan area). B, separated curves for subgroups with saphenofemoral junction < 8 mm or ≥ 8 mm. No statistical difference was observed between groups. Ticks represent censored individuals.

Occlusion and recanalization rate

Seventeen (56%) patients presented with occlusion of the treated vein in the 1st month, 11 (36%) in the 3rd month, and 9 (30%) in the 6th month of follow-up.

Healing and recurrence of ulcers

The average time for ulcers to heal was 90 days, ranging from 18 to 245 days. Of the 28 participants treated, the ulcer healed in 17 (56,6% of 30 treated legs). Figure 2 shows the Kaplan-Meier curve analysis of ulcer healing until one year of follow-up. Although patients with SFJ ≥ 8 mm showed an increased ulcer healing rate than those with SFJ < 8mm, no statistical difference was observed (log-rank, p = 0,178).

Three (10%) patients presented with ulcer recurrence up to the 6th month. The average period for recurrence was five months. These patients had no other complications during follow-up, and their GSV diameters before treatment were 6.5, 8.2, and 11.6 mm.

Two patients developed chemical phlebitis at the puncture site, one patient complained of pain in the ankle after the session, and another patient presented with a mild cough. No complications were reported with systemic repercussions. There were no reports of any complications in subsequent follow-ups at one, three, and six months after treatment.

DISCUSSION

Foam sclerotherapy is a minimally invasive therapeutic modality for CVI with an efficacy similar to other treatments, and it can be applied to patients with advanced age and contraindications to conventional surgery[15]. The occlusion of incompetent superficial veins improves ulcer healing and venous symptoms[26]. There is no consensus regarding the limits for the benefit of sclerotherapy and the cutoff point to consider large GSV diameters has been described to be between 5.5 and 12 mm in the literature[23,27].

Regarding the CVI severity score, the study by Abreu et al.[28] showed a reduction in the score in all 22 patients who underwent sclerotherapy after 180 days compared to pretreatment. Similar results were reported by Silva et al.[7], with a reduction in the mean VCSS from 18.7 to 7.5 after treatment. A significant reduction was observed in this sample in the 1st-, 3rd-, and 6th-month follow-up scores.

The study by Coelho Neto et al.[29] reinforce the power of sclerotherapy regarding pain improvement. Before treatment, 25% of patients reported being free of pain or having only very mild pain; on the other hand, after 45 days, it increased to 56% of the patients[29]. This study maintained that reported pattern, with significant differences in the VCSS pain parameter in the follow-up, compared to the pretreatment, with a progressive reduction in the score throughout the study follow-up period.

Few studies have analyzed the influence of the GSV diameter in minimally invasive treatments. Shaidakov et al.[22] compared patients with a GSV diameter ≥ 14 mm who underwent radiofrequency

ablation and surgical treatment after one year; 64 and 65 patients were analyzed, respectively, and it was concluded that ablation was superior to surgical treatment concerning the analyzed outcomes (vessel obliteration/vessel absence, pain, subcutaneous hemorrhage, and paresthesia) in large-diameter saphenous veins[22].

Shadid et al.[20] observed that the treatment of incompetent GSV was less effective in the recurrence of reflux in patients with diameter > 6 mm and with distal reflux after two years of follow-up. However, that study was mainly composed of participants with CEAP C2-C4, different from the present study sample, which is limited to CEAP C6[20].

Woo et al.[23] analyzed the impact of the diameter of the GSV on patients undergoing radiofrequency ablation. For this, the participants were divided into two subgroups according to diameter: 663 with GSV ≤ 12 mm and 59 with GSV > 12 mm, predominantly CEAP C1 and C2. There was no difference between the subgroups regarding occlusion rates, complications, or clinical improvement at the 12-month follow-up[23]. Accordingly, no significant difference was observed in this sample regarding the severity of venous symptoms after sclerotherapy between the subgroups of SFJ < 8 mm and ≥ 8 mm.

Attaran et al.[27] found no difference between groups of patients with a GSV diameter < 5.5 mm and ≥ 5.5 mm treated with ablation concerning symptom relief and VCSS. A weak correlation between GSV diameter and VCSS was also identified before treatment and after 36 months. Larger incompetent veins are believed to be more symptomatic; however, recent studies have presented discordant findings[27].

Previous studies reported a recanalization rate of 31.5% in an average follow-up period of 460 days[12]. Howard et al.[30] observed a complete recanalization of 12% and partial recanalization in 27% of 93 participants after one year. Partial and complete recanalization rates of 17.3% and 7.7%, respectively, were recorded after six months in their sample.

Long-lasting venous ulcers, associated infections, low adherence to compressive therapy, high BMI values, and great depth were associated with long-term healing[31,32]. The rate of ulcer healing in the literature ranged between 77.27% and 89%, with an average time of 31.4 to 37 days[7,12,28], rather than the 56.7% in this sample. This lower healing rate and a longer healing time may be influenced by the worse prognostic factors in our cohort mentioned above.

Abreu et al.[28] showed healing of 77.27% of ulcers in 6 months of follow-up of 22 CEAP C6 patients with an average VSM diameter of 11 mm. Our study showed an ulcer healing rate of 56.6%, in an average of 3 months.

This study has several limitations. The number of participants was small and may limit the statistical analysis of the data. There was little adherence by patients to the stipulated post-procedure follow-up, in addition to limited public funding for sclerotherapy with foam in the service and difficulty in performing additional tests.

Knowledge of the predictive factors for the success of treatment for CVI is still limited, and in the future, it may improve the choice of treatment. Additional studies are needed on the impact of the diameter of the VSM for treating CVI, with controlled and randomized trials and direct comparisons with other minimally invasive treatment modalities.

CONCLUSION

Our results suggest no difference between the subgroups by GSV diameter in terms of symptom severity, with a significant reduction in VCSS and a reduction in pain after foam sclerotherapy in both groups. There was no significant difference between subgroups regarding ulcer healing. Due to the study limitations, more robust studies are needed to investigate the impact of GSV diameter on CVI treatment.

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