

## Complications of Sclerotherapy with Sclerosing Foam in Lower Extremity Varicose Veins

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<i>Article information</i>	<i>Abstract</i>
<p>Article history:                      Received: 24 Feb 2013                      Accepted: 8 June 2013                      Available online: 9 Dec 2013                      ZJRMS 2015 Jan; 17(1): 27-29</p> <p>Keywords:                      Sclerotherapy                      Sclerosing foam                      Varicose branches                      Lower extremity</p> <p>*Corresponding author at:                      Department of Surgery, Guilan                      Road Trauma Research Center,                      Guilan University of Medical                      Sciences, Guilan, Iran.                      E-mail:  <a href="mailto:hemmati@gtrc.ir">hemmati@gtrc.ir</a></p>	<p><b>Background:</b> Using sclerotherapy with foam has caused a great change in treatment of varicose veins. Although, it is more than a century that it is being used, no exact and comprehensive knowledge of its complications has been published yet with regard to the existing facilities in Iran.</p> <p><b>Materials and Methods:</b> In this cross-sectional study, Patients with varicose veins of lower extremity referred to cardiology clinic of Razi hospital, Rasht were included in the study after doppler sonography and in case of presence of varicose veins with more than 2 mm diameter in lower extremities without inadequacy of saphenofemoral and saphenopopliteal valve. They then underwent sclerosing with foam treatment. The total number of patients was 156 who were examined 2 weeks and 3 months after sclerotherapy in terms of complications such as pain, pigmentation, recurrence, phlebitis, deep vein thrombosis and skin necrosis.</p> <p><b>Results:</b> Out of 156 patients, 47 were men and 109 women whose mean±SD age was 46.5±12.2 years. Two weeks after sclerotherapy, pain in 95 patients (65.1%), pigmentation in 79 patients (53.4%), recurrence in 5 patients (3.4%), necrosis in 8 patients (5.5%) and no phlebitis was witnessed. Three months after sclerotherapy, pain in 10 patients (6.8%), pigmentation in 52 patients (35.1%), recurrence in 13 patients (8.8%) and phlebitis in 13 patients (8.8%) were seen; however, necrosis was not observed</p> <p><b>Conclusion:</b> Sclerotherapy with foam is an effective, safe and inexpensive method for treatment of varicose veins of lower extremities. Thus, in case of a careful selection of patients and conduction in an equipped center, few complications will be seen.</p> <p style="text-align: right; font-size: small;">Copyright © 2015 Zahedan University of Medical Sciences. All rights reserved.</p>

### Introduction

Varicose vein of the lower extremity is a common disease. Ten to 35% of adults have some degrees of chronic venous insufficiency [1, 2]. Its high-cost treatment is a burden on medical system (annually one million dollars in U.S.) plus the disadvantages of lost working days due to this disease (about 4.6 working days in U.S.) [3, 4].

In past decade, the treatment of varicose veins has undergone significant changes. Using new methods for treatment of varicose veins with laser, radiofrequency and sclerotherapy have opened new horizons in treatment of these patients [5, 6].

Sclerotherapy is injection of a caustic solution (sclerosing) into a varicose vein which causes inflammation and localized damage of the intima of the vein, causing obstruction. It is about a century that this method is being used for treatment of varicose veins [7]. The widespread use of sclerosing foam has begun from the previous decade [7, 8]. Sclerotherapy with foam is injection of a sclerosing mixed with air into an abnormal vein which causes damage and obstruction of the intima of vein [7, 9, 10].

Possible treatment of varicose veins with greater diameter (>2 mm), easier use, less complications, and

higher effectiveness with lower drug doses have made foam sclerotherapy a very useful method for treatment of these veins. This is an outpatient procedure without anesthesia and with minimal discomfort in patients who can soon return to their jobs [11-14].

### Materials and Methods

Patients with varicose veins of lower extremities who were referred to cardiology clinic of Razi hospital (2009 until 2010), Rasht were included in the study after Doppler sonography and in case of presence of varicose veins with more than 2 mm diameter in lower extremities without inadequacy of saphenofemoral and saphenopopliteal valves. They then underwent sclerosing with foam.

The total number of patients was 156; 47 were men and 109 women. Three patients did not referred on time for 2 week follow-up and 5 ones for 3rd month follow-ups. Quantitative data as mean±SD and qualitative variables were expressed as frequencies. We used  $\chi^2$  exam and Fisher's exact test for statistical analysis. The data were analyzed by using the SPSS-16 software and data were considered significant with  $p$ -value≤0.05.

## Results

In this study, patients with varicose veins of lower extremities who were referred to cardiology clinic of Razi hospital, Rasht were included in the study after Doppler sonography and in case of presence of varicose veins with more than 2 mm diameter in lower extremities without inadequacy of saphenofemoral and saphenopopliteal valves. They then underwent sclerosing with foam.

The total number of patients was 156; 47 were men and 109 women. Three patients did not referred on time for 2 week follow-up and 5 ones for 3rd month follow-ups. Most of subjects were women (69.9%). In a way that female population was averagely observed more compared to male (33.38-43.77%). The mean±standard deviation of age was 46.5±12.2 years. The minimum age of referees was 20 years and the maximum 76 years. There was a statistically significant difference between low pain frequency (without sedatives) between 2 weeks and 3 months after sclerotherapy ( $p<0.0001$ ) in a way that less pain frequency within 2 weeks after sclerotherapy (65.1%) was 9.6 times more than that of 3 months after sclerotherapy (6.8%). The findings suggest that 95% standard deviation of little pain (without sedatives) in patients suffering varicose veins of lower extremities with foam sclerotherapy treatment was 56.5%, 71.9% two weeks after treatment and 11.5%, 3.1% three weeks after treatment.

Pigmentation frequency of the samples was statistically significant in terms of the measurement time ( $p<0.0001$ ) so that it declined about 20% three months after sclerotherapy (35.1%) compared to 2 weeks after sclerotherapy (53.4%).

On the other side, the results show that the recurrence rate of varicose veins in 2 measurement times was not statistically significant ( $p<0.03$ ). Based on 95% confidence interval (CI), the recurrence rates of varicose veins in 2 weeks after treatment were 6.1%, 0.42% and three months after treatment were 13.1%, 4.08%.

The amount of phlebitis was statistically significant at the time of measurement ( $p<0.0001$ ). In a way that phlebitis frequency in 2 measurement times was not statistically significant and after 3 months phlebitis increased to 8.8%. According to 95% CI, phlebitis was 0% in two weeks after sclerotherapy and 13.1% and 4.08% three months after treatment. Deep vein thrombosis was not observed in the samples in two measurement times.

Results demonstrated that the extent of skin necrosis in both measurement times was significant ( $p<0.008$ ). Frequency of skin necrosis in 2 weeks after sclerotherapy was approximately 5.5% while this rate changed to 0% in three months after sclerotherapy. Moreover, based on 95% CI, skin necrosis was 10.6% and 2.6% two weeks after sclerotherapy and 0% three months after treatment.

## Discussion

In this study, 156 patients (47 men and 109 women) with the age of 47±12 years due to presence of varicose

veins with a diameter of 2 mm in lower limbs without inadequacy of saphenofemoral and saphenopopliteal valves underwent foam sclerosing treatment. Results revealed that the complications of this method are few which improve by the time. However, the risk of recurrence rate increases over time.

During the past decade, foam sclerotherapy has become an effective method in treatment of varicose and inadequate veins. This method can be used to treat large and small varicose veins and even saphenous vein trunk, inadequate perforating veins and ulcers due to venous stasis and its serious consequences are rare. The drawback of this technique is that in many cases there is a need for multiple injections. Furthermore, U.S. Food and Drug Administration (FDA) has not approved all of the agents of sclerosing. The advantages of foam sclerotherapy consist of low cost, no need to anesthesia and hospitalization, fast recovery and easy use. Today, it is considered an important therapeutic tool in treatment of varicose veins [15].

Foam sclerosing has features which makes it more effective than the liquid sclerosing. Unlike the latter, the former transfers blood in vein lumen and is not diluted by blood. Thus, it sticks to the walls of veins and increases the ability of veins' spasm. The ability of foam to enter collateral veins makes it more widespread in a wider surface [16].

Studies which compared the effectiveness and safety of foam sclerotherapy to liquid sclerotherapy have unveiled that even with the presence of few sclerosing used in foam sclerotherapy, it was clearly more effective than liquid sclerotherapy (20-50%). Complications of the two methods had no difference in existing studies; however, blurred vision was more common in foam sclerotherapy. Thus, the effectiveness of sclerotherapy with foam is more than sclerotherapy with liquid [17].

Although this study did not examine the effect of sclerotherapy in improvement of varicose ulcers, in other studies the improvement of such ulcers with minimal complications by foam sclerotherapy has been reported [16].

Despite of employing techniques such as microthrombectomy, in other studies aiming at reduction of amount of pigmentation, the amount of this complication did not show any significant difference (49%) in this study after 3 months (35.1%), thus imposing an additional painful procedure in continuing sclerotherapy does not seem justified [18].

Recurrence of varicose vein in all types of treatments is a universal concern. Although the study did not use the standardized industrial foam, recurrence of varices 2 weeks after sclerotherapy (3.4%) and 3 months after sclerotherapy (8.8%) had no remarkable difference (5.6%) compared to other studies [18]. Deep vein thrombosis (DVT) was not present in our study [18]. This could be due to the type of treated veins (reticular and telangiectasia) and low dose of sclerosing agent used in foam method. Skin necrosis is a rare but significant complication in sclerotherapy with foam (0.2-1.2%) [18].

In present study, in areas of foam sclerotherapy, necrosis was not observed; however, where fluid sclerosing was used for treatment of fine telangiectasia to complete sclerotherapy, minor skin necrosis was seen in 5.5% of patients in 2 weeks follow-up, all of which improved without surgical intervention 3 months after the injection. Therefore, preoperative counseling is recommended especially in patients undergoing telangiectasia treatment along with sclerotherapy of larger veins with foam.

One of the benefits of sclerotherapy compared to surgical procedures is that it is less painful plus the ability to perform on outpatient basis. Although in various studies, the pain in sclerotherapy with liquid was less than sclerotherapy with foam, the amount of pain in our patients in follow-up periods after foam sclerotherapy was similar to other studies. High effectiveness of foam sclerotherapy well compensates for this shortcoming. Furthermore, this amount of pain compared to surgical procedures can easily be negligible [18]. The incidence of phlebitis after sclerotherapy with foam has also been reported 66% [19]. But this complication in present study was 8.8% in 3 month follow-up which can be due to

lower concentration of sclerosing foam, emphasis on constant bandage and 48 h rest after sclerotherapy. Although in many studies, by adopting appropriate technique this problem has not been reported [19].

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### Authors' Contributions

All authors had equal role in design, work, statistical analysis and manuscript writing.

### Conflict of Interest

The authors declare no conflict of interest.

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### References

- White GH. Chronic venous insufficiency. In: Veith FJ, Hobson RW, Williams RA, editors. Vascular surgery. Principles and practice. 2<sup>nd</sup> ed. New York: McGraw-Hill; 1993: 865-888.
- Callam MJ. Epidemiology of varicose veins. Br J Surg. 1994; 81(2): 167-173.
- Hume M. Presidential address: A venous renaissance? J Vasc Surg. 1992; 15(6): 947-951.
- Lawrence PF, Gazak CE. Epidemiology of chronic venous insufficiency. In: Gloviczki P, Bergan JJ. Atlas of endoscopic perforator vein surgery. 1<sup>st</sup> ed. USA: Springer; 1998: 31-44.
- Petrovic S, Chandler JG. Endovenous obliteration: An effective, minimally invasive surrogate for saphenous vein stripping. J Endovasc Surg. 2000; 7: 11.
- Goren G, Yellin AE. Primary varicose veins: Topographic and hemodynamic correlations. J Cardiovasc Surg. 1990; 31(5): 672-7.
- Goldman MP, Bergan JJ. Sclerotherapy: Treatment of varicose and telangiectatic leg veins. 3<sup>rd</sup> ed. USA: Mosby; 2001.
- Rautio T, Ohinmaa A, Perala J, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: A randomized, controlled trial with comparison of the costs. J Vasc Surg. 2002; 35(5): 958-65.
- Gibson KD, Ferris BL, Pepper D. Foam sclerotherapy for the treatment of superficial venous insufficiency. Surg Clin North Am. 2007; 87(5): 1285-1295.
- Kahle B, Leng K. Efficacy of sclerotherapy in varicose veins-a prospective, blinded, placebo-controlled study. Dermatol Surg. 2004; 30(5): 723-728.
- Orbach EJ. Sclerotherapy of varicose veins: Utilization of an intravenous air block. Am J Surg. 1944; 66(3): 362-366.
- Wright D, Gobin JP, Bradbury AW, et al. Varisolve polydocanol microfoam compared with surgery or sclerotherapy in the management of varicose vein in the presence of trunk vein incompetence: European randomized controlled trial. Phlebology. 2006; 21(4): 180-90.
- Jia X, Mowatt G, Burr JM, et al. Systematic review of foam sclerotherapy for varicose veins. Br J Surg. 2007; 94(8): 925-936.
- Hartweger EW. [A contribution to the therapy of the varicose symptom complex] German [Abstract]. Dtsch Med J. 1965; 16(20): 654-5.
- Gibson KD, Ferris BL, Pepper D. Foam sclerotherapy for the treatment of superficial venous insufficiency. Surg Clin North Am. 2007; 87(5): 1285-95.
- Nael R, Rathbun S. Effectiveness of foam sclerotherapy for the treatment of varicose veins. Vasc Med. 2010; 15(1): 27-32.
- Hamel-Desnos C, Allaert FA. Liquid versus foam sclerotherapy. Phlebology. 2009; 24(6): 240-6.
- Alòs J, Carreño P, López JA, et al. Efficacy and safety of sclerotherapy using polydocanol foam: A controlled clinical trial. Eur J Vasc Endovasc Surg. 2006; 31(1): 101-107.
- Uurto I, Hannukainen J, Aarnio P. Single-center experience with foam sclerotherapy without ultrasound guidance for treatment of varicose veins. Dermatol Surg. 2007; 33(11): 1334-9.

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