From the American Venous Forum

Treatment pattern of consecutive patients with chronic venous disease

Joel M. Crawford, MD, Antonios Gasparis, MD, Sahar Amery, MD, *and* Nicos Labropoulos, PhD, *Stony Brook, NY*

ABSTRACT

Background: No clear data exist on the treatment patterns in patients with chronic venous disease. This study was designed to determine how such patients were treated in our center.

Methods: Consecutive patients presenting for a vein consultation at our center were collected during a 9-month period, allotting for at least 6 months of follow-up. All patients had a detailed history and physical examination by experienced vascular surgeons and a complete venous ultrasound evaluation by registered vascular technologists having experience in venous imaging. Charts were reviewed for patient factors including body mass index, age, clinical class (Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classification), and treatment. Deidentified data from the chart review were entered into a local database. Queries were designed to identify trends in the data. The results of the queries were exported to a spreadsheet program for analysis per patient and per limb.

Results: There were 506 patients evaluated for venous disease during a period of 9 months. We identified 200 patients with chronic venous disease who required superficial vein treatment. There were 136 (68%) women. Ablation was required in 156 patients (78%), whereas 44 (22%) required only adjunctive therapy (microphlebectomy or sclerotherapy). The average number of ablations in patients with venous disease was 1.3 (259 ablations in 200 patients). In patients who needed at least one ablation, the average was 1.7 ablations per patient (259 ablations in 156 patients). Unilateral ablation was done in 94 patients (60%), and 62 patients (40%) had bilateral treatment. Of those who underwent unilateral ablations, 61% required adjunctive treatment of the contralateral limb. In patients who required only adjunctive therapy (no ablation), 73% underwent bilateral treatment. There were 182 limbs (45.5%) that did not require ablation as no reflux was found in the saphenous systems. Of the 156 patients who underwent ablation, 218 limbs had at least one ablation; 52% of limbs had C2 disease and on average underwent 1.1 ablations/limb. Only 7 of 113 (6%) limbs required more than one ablation. Average ablations per limb increased with clinical class, C3 having 1.2 ablations/limb, C4 having 1.4 ablations/limb, and C5 and C6 having 1.56 ablations/limb.

Conclusions: Patients with venous disease required on average 1.3 ablations/patient. Most (78%) require at least one ablation for an average of 1.7 ablations/patient. There were 182 limbs (45.5%) with no saphenous reflux that did not require an ablation. The average number of ablations/limb increased with CEAP class. (J Vasc Surg: Venous and Lym Dis 2018;■:1-5.)

Keywords: Endovenous; Ablations; Average; Vein; Center

The treatment patterns in patients with chronic venous disease (CVD) vary with the practice and type of referral. Cross-sectional studies looking at ablation practices in the United States as well as in other countries have been performed, but these have been limited. Demographics, disease, selection criteria, and reasons that patients were excluded from the analysis have not been reported. Therefore, a realistic view on the number of cases that could be treated with endovenous ablation is lacking. Such information is important because it demonstrates the reason for ablations to be performed per patient and in each limb. Values of this kind are needed to depict the treatment patterns and to establish thresholds for undertreatment and, particularly nowadays, overtreatment. This study was designed to determine how consecutive patients with signs and symptoms of CVD were treated in our center.

METHODS

Consecutive patients presenting for a vein consultation at our center were collected during a 9-month period, allotting for at least 6 months of follow-up. All patients had a detailed history and physical examination by experienced vascular surgeons and a complete venous ultrasound evaluation by registered vascular technologists having experience in venous imaging. The charts were reviewed by a physician for patient factors including body mass index (BMI), age, clinical class (Clinical, Etiology, Anatomy, and Pathophysiology

From the Division of Vascular Surgery, Department of Surgery, Stony Brook University.

Author conflict of interest: none.

Presented at the Thirtieth Annual Meeting of the American Venous Forum, Tucson, Ariz, February 20-23, 2018.

Correspondence: Nicos Labropoulos, PhD, Stony Brook University, 101 Nicolls Rd, HSC T-19, Rm 90, Stony Brook, NY 11794 (e-mail: nlabrop@yahoo.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

https://doi.org/10.1016/j.jvsv.2018.08.011

[CEAP] classification), and treatment. Institutional Review Board approval was obtained. The study was exempt from informed consent. Inclusion criteria for ablation included the following: patient presented for evaluation of venous complaints, symptomatic, saphenous reflux, saphenous vein diameter of 5 to 20 mm, reflux >2 seconds, and reflux segment >10 cm. Exclusion criteria included failure to complete treatment, cosmetic treatment only, confounding disease present, and C0 or C1 disease. Deidentified data from the chart review were entered into a local database. Queries were designed to identify trends in the data. The results of the queries were exported to a spreadsheet program for analysis.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective cohort study
- **Take Home Message:** In an academic medical center during 9 months, 182 of 506 patients with venous disease (45.5%) had no saphenous reflux; 200 were treated for superficial vein disease (156 [78%] with ablation, 44 [22%] with microphlebectomy or sclerotherapy), with an average 1.3 ablations per treated patient (259 ablations in 200 patients). There were 1.7 ablations per patient treated with ablation, with more ablations in those with higher Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classes.
- **Recommendation:** Almost half the patients evaluated in a venous clinic will not have saphenous reflux, and those requiring ablation averaged 1.7 ablations/patient. Ablations increased with increasing CEAP class. These data could serve as a benchmark to avoid overtreatment.

RESULTS

There were 506 patients evaluated for venous disease during a period of 9 months. We identified 200 patients with CVD who would benefit from superficial vein treatment by ablation, microphlebectomy, or sclerotherapy (Fig 1). There were 136 (68%) women. The average age was 54 years; 63 patients had undergone previous treatment. Ablation was required in 156 patients (78%), whereas 44 (22%) required only adjunctive therapy (microphlebectomy or sclerotherapy). The average number of ablations in patients with venous disease was 1.3 (259 ablations in 200 patients). Patients who had undergone previous treatment had an average of 1.3 ablations. Those who had not undergone previous treatment also had an average of 1.3 ablations. In patients who needed at least one ablation, the average was 1.7 ablations per patient (259 ablations in 156 patients). Unilateral ablation was done in 94 patients (60%), and 62 patients (40%) had bilateral treatment. There was no difference in the number of ablations/limb whether it was bilateral (1.28/limb) or unilateral (1.38/limb). Of those who underwent unilateral ablations, 61% required adjunctive treatment of the contralateral limb. In patients who required only adjunctive therapy (no ablation), 73% underwent bilateral treatment. There were 182 limbs (45.5%) that did not require ablation as no reflux was found in the saphenous systems. Of the 156 patients who underwent ablation, 218 limbs had at least one ablation.

The majority of limbs (52%) had C2 disease and on average underwent 1.1 ablations/limb (Fig 2). Only 7 of 113 (6%) limbs in C2 required more than one ablation.

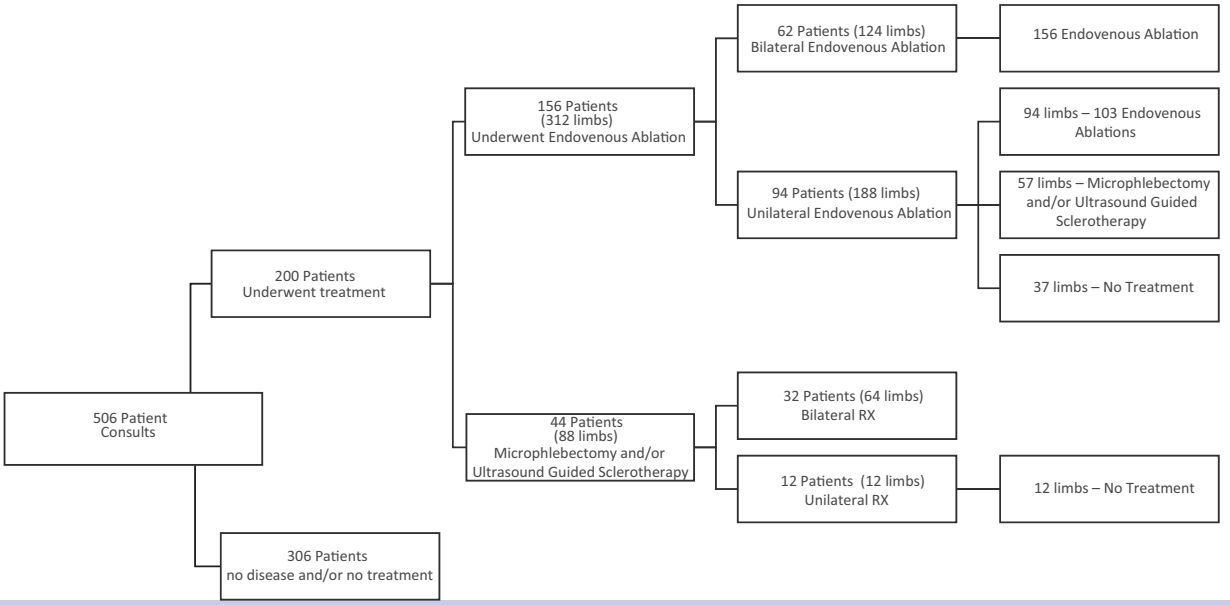

Fig 1. Flow chart of the management of patients. *RX,* Treatment.

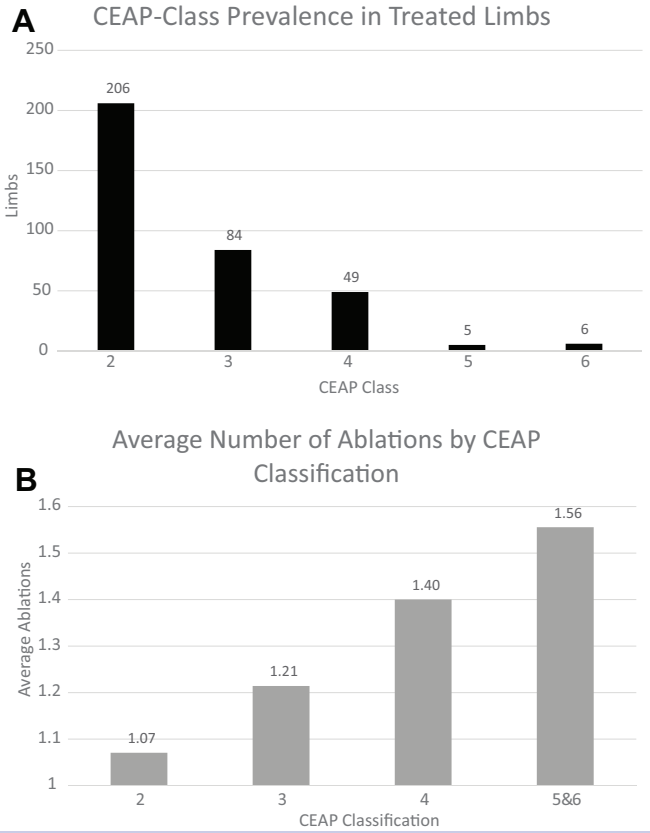

Fig 2. A, Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) class distribution (C2-C6) in limbs of 200 patients with chronic venous disease (CVD). Excluded C0 and C1 limbs totaled 50. **B,** Number of ablations per limb in each CEAP class.

Average ablations per limb increased with clinical class, C3 having 1.2 ablations/limb, C4 having 1.4 ablations/limb, and C5 and C6 having 1.56 ablations/limb (Fig 2, *B*). With regard to age, a rise was seen with ablations per patient (Fig 3). The number of patients with CVD for each decade of life is shown in Fig 4. In looking at clinical class in regard to age, the average age was higher with increasing severity (Fig 5). A rise was seen similarly in average ablations per patient until BMI >44 kg/m^2 (Table).

DISCUSSION

In our venous practice, 32% of patients underwent venous ablation. The 68% of the patients who did not need ablation included those seeking cosmetic improvement, patients with tributary disease alone or nonsaphenous vein reflux, patients with swelling not related to venous disease, and morbidly obese patients. The distribution of disease among patients presenting to our center is consistent with other studies.[1-3] It would be fair to state that most patients visiting a vein clinic as a primary vascular consultation do not require endovenous ablation. This is because patients do not want treatment at that moment, the patients cannot afford to pay (they have no insurance, or insurance does not cover treatment), or the patient is superobese without skin damage. Other factors include lymphedema, systemic diseases such as right-sided heart failure, deep vein obstruction without or with limited superficial vein reflux, and edema from other causes; a pathologic process out of proportion with the ultrasound findings; skin conditions mimicking CVD; medication producing similar signs and symptoms; and other rare nonvenous disease. Given these data, when one observes a higher rate of ablation (ie, two or more ablations in most patients) in consecutive patients of a vein center, it may indicate overtreatment. A few patients may require more than two ablations; however, this should not represent the majority of the practice.

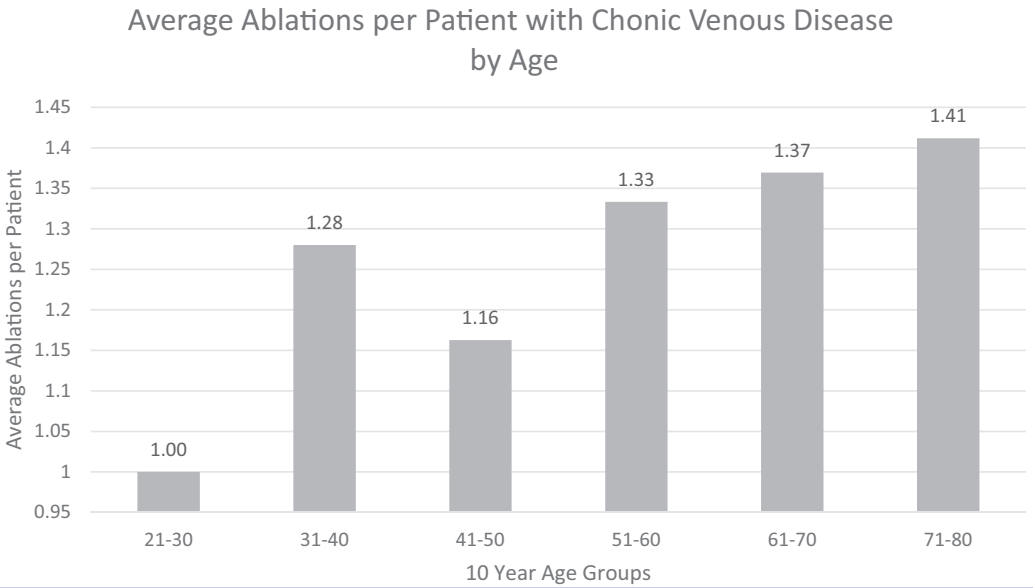

Fig 3. Average number of ablations per patient in each decade of life.

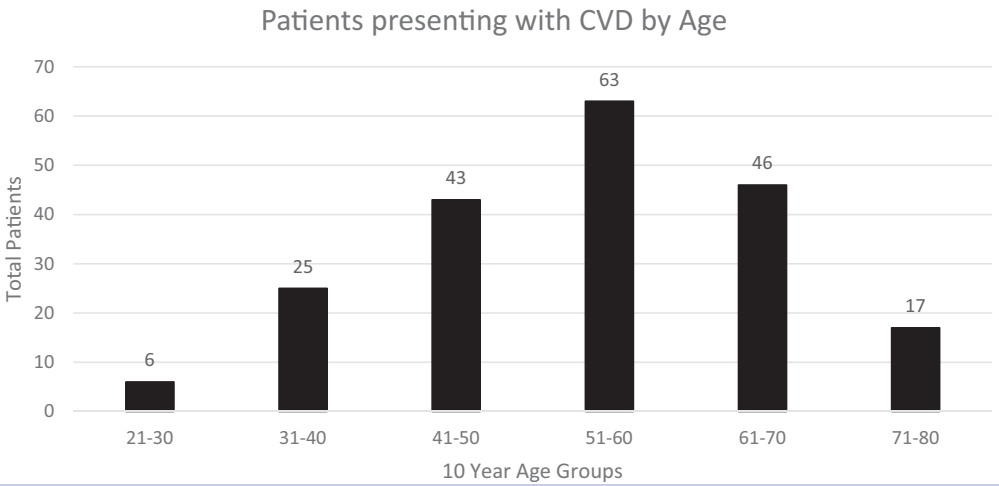

Fig 4. Number of patients (C2 or higher) requiring ablation, phlebectomies, or sclerotherapy in each decade of life. *CVD*, Chronic venous disease.

An increase in ablations per patient was seen with age and CEAP class. This is probably expected as the age of patients increases with CEAP class. Several studies have demonstrated that patients with skin damage and ulceration are older than those having varicose veins.[4-6] Patients with advanced disease have more sites of reflux and are likely to undergo a higher number of ablations. However, the majority of practices in the United States likely treat mostly patients with C2 and C3 disease.

Most patients who had previous treatment performed by another provider lacked documentation or accurate knowledge of what their treatment was. Despite having previous treatment, their ablation rate was no different from that of those with no treatment. Patients with previous interventions may have reflux in the untreated limb and recurrent, residual, or new disease in the ipsilateral limb. Such a finding should be treated with caution as it is seen as a one-time event without knowledge of the original disease.

The trend with ablations related to BMI is interesting but probably not of major significance. The drop-off seen after BMI of 45 kg/m^2 is due to our practice pattern of ablating the superobese only in cases of ulceration as other CVD symptoms are unlikely to improve without weight loss.

On average, 1.7 ablations were performed in patients who needed such a procedure. We previously found similar data after analyzing the Medicare Provider Utilization and Payment database. In the database, the average ablations per patient of the aggregate data set were 1.8.[7] As of December 2017, there were 58 million Medicare recipients who made up approximately 18% of the population, indicating that a large number of venous disease is from this group.

Intention-to-treat analysis was not performed before treatment to determine whether the findings were appropriate. This could not be done because of the retrospective nature of our study. Even if we assume that we somewhat overtreat, our average still remains below that seen in the Medicare data.

It is our practice to avoid ablation in segmental reflux in the saphenous trunks or accessory veins. Saphenous veins can have segmental reflux or be normal with reflux in varicosities alone.[8,9] In these cases, we treat the

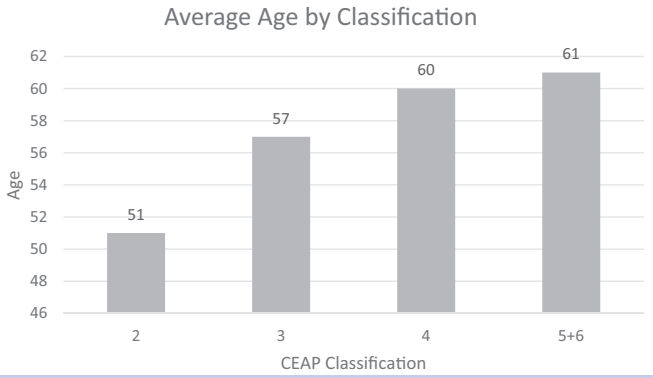

Fig 5. Average age of patients in each Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) class.

Table. Prevalence of ablations and patients in body mass index (*BMI*) categories

BMI, kg/m^2	Average ablations	Patients	Ablations
18-24	1.13	47	53
25-29	1.15	80	92
30-34	1.43	37	53
35-39	1.75	20	35
40-44	2.33	9	21
45-49	0.33	3	1
50-54	1.00	2	2
55-59	1.00	1	1
60-64	0.00	0	0
65	1.00	1	1

varicosities in anticipation of resolving the segmental reflux. This has been shown in several studies to be an effective method of treatment and reduces the use of ablation.[10-12]

The results cannot necessarily be generalized to every practice and should not be used to define appropriateness. Regional variation does exist in patients seeking treatment for their venous disease, and significant variation can be seen in neighboring practitioners according to specialization. A dedicated vein center like ours, in which all types of treatment for venous disease have been performed for 15 years, may not represent the norm of an average vein clinic in the country. Clearly, for many practitioners in the United States with different types of training and expertise, both the type of referrals and the clinical outcomes may vary significantly. Unfortunately, there is no formalized dedicated venous training, nor is it dictated who can perform venous treatment. We do like to believe that these results can be a guide to what practitioners should expect in consecutive patients with CVD in a vein clinic. Some practices may have more patients with skin damage, whereas others may have more patients with cosmetic issues. The data in this study most likely represent a realistic image of consecutive patients with CVD in the Western world. Furthermore, our results may differ from other reports as only patients with >2 seconds of reflux were treated. We believe that the volume of blood shifted in a short duration of reflux may not account for the patient's symptoms.

The main limitation in this study is its retrospective nature and short-term follow-up. Although these data provide a good guide of what one should expect for the different patterns of treatment, more accurate and detailed information could be given only in a prospective study. A longer follow-up would have allowed more procedures to be performed per patient. Clearly, up to 30% of patients will have recurrence or development of new disease at 5 years. However, the clinical presentation is most often milder than the original. Such patients may be asymptomatic, require cosmetic treatment, or need intervention for symptomatic disease. Given that at 5 years the number of procedures would increase at a moderate degree, the number of ablations would change by only a modest amount. A detailed analysis of anatomic reflux patterns is an opportunity for further research. This could be used to provide recommendations on appropriateness of treatment.

CONCLUSIONS

Patients with venous disease required on average 1.3 ablations/patient. Most (78%) require at least one ablation for an average of 1.7 ablations/patient. There were 182 limbs (45.5%) with no saphenous reflux that did not require an ablation. The average number of ablations/limb increased with CEAP class.

AUTHOR CONTRIBUTIONS

Conception and design: JC, AG, NL
Analysis and interpretation: JC, NL
Data collection: JC, SA
Writing the article: JC, NL
Critical revision of the article: JC, AG, SA, NL
Final approval of the article: JC, AG, SA, NL
Statistical analysis: JC, NL
Obtained funding: Not applicable
Overall responsibility: JC

REFERENCES

1. Criqui M, Jamosmos M, Fronek A, Denenberg JO, Langer RD, Bergan J, et al. Chronic venous disease in an ethnically diverse population: the San Diego Population Study. Am J Epidemiol 2003;158:448-56.
2. Rabe E, Pannier F, Ko A, Berboth G, Hoffmann B, Hertel S. Incidence of varicose veins, chronic venous insufficiency, and progression of the disease in the Bonn Vein Study II. J Vasc Surg 2010;51:791.
3. Lee AJ, Robertson LA, Boghossian SM, Allan PL, Ruckley CV, Fowkes FG, et al. Progression of varicose veins and chronic venous insufficiency in the general population in the Edinburgh Vein Study. J Vasc Surg Venous Lymphat Disord 2015;3:18-26.
4. Labropoulos N, Delis K, Nicolaides AN, Leon M, Ramaswami G. The role of the distribution and anatomic extent of reflux in the development of signs and symptoms in chronic venous insufficiency. J Vasc Surg 1996;23:504-10.
5. Labropoulos N, Patel PJ, Tiongson JE, Pryor L, Leon LR Jr, Tassiopoulos AK. Patterns of venous reflux and obstruction in patients with skin damage due to chronic venous disease. Vasc Endovascular Surg 2007;41:33-40.
6. Danielsson G, Eklof B, Grandinetti A, Lurie F, Kistner RL. Deep axial reflux, an important contributor to skin changes or ulcer in chronic venous disease. J Vasc Surg 2003;38:1336-41.
7. Crawford JM, Gasparis A, Almeida J, Elais S, Wakefield T, Lal BK, et al. United States endovenous ablation practice trends: 4-year review of Medicare provider utilization and payment database. J Vasc Surg Venous Lymphat Disord 2018;6:288.
8. Labropoulos N, Giannoukas A, Delis K, Mansour M, Kang S, Nicolaides A, et al. Where does venous reflux start? J Vasc Surg 1997;26:736-42.
9. Labropoulos N, Leon L, Engelhorn CA, Amaral SI, Rodriguez H, Kang SS, et al. Sapheno-femoral junction reflux in patients with a normal saphenous trunk. Eur J Vasc Endovasc Surg 2004;28:595-9.
10. Pittaluga P, Chastanet S, Locret T, Barbe R. The effect of isolated phlebectomy on reflux and diameter of the great saphenous vein: a prospective study. Eur J Vasc Endovasc Surg 2010;40:122-8.
11. Pittaluga P, Chastanet S, Rea B, Barbe R. Midterm results of the surgical treatment of varices by phlebectomy with conservation of a refluxing saphenous vein. J Vasc Surg 2009;50:107-18.
12. Biemans AA, van den Bos RR, Hollestein LM, Maessen-Visch MB, Vergouwe Y, Neumann HA, et al. The effect of single phlebectomies of a large varicose tributary on great saphenous vein reflux. J Vasc Surg Venous Lymphat Disord 2014;2:179-87.

Submitted Apr 24, 2018; accepted Aug 29, 2018.