Endovenous Laser Ablation with and Without Concomitant Phlebectomy for the Treatment of Varicose Veins: A Retrospective Analysis of 954 Limbs

Yohei Kawai,[1] Masayuki Sugimoto,[1] Kiyoshi Aikawa,[2] and Kimihiro Komori,[1] Nagoya, Japan

Background: Endovenous laser ablation (EVLA) with concomitant phlebectomy is commonly performed in many institutions. However, phlebectomy is associated with cosmetic complications such as surgical scarring, hemorrhage, and hematoma. This study aims to compare the need for additional sclerotherapy during follow-up after EVLA with and without concomitant phlebectomy.

Methods: Between November 2013 and December 2018, we performed EVLA on 1,363 limbs in 1,009 patients with symptomatic primary varicose veins, of which 954 limbs in 771 patients with great saphenous vein (GSV) or small saphenous vein (SSV) insufficiency were included in this study. Data were collected prospectively and supplemented with retrospective medical record review. Demographic and clinical characteristic profiles were collected. The outcomes of EVLA with or without concomitant phlebectomy were compared. Logistic regression was used to assess predictors for additional sclerotherapy after EVLA.

Results: CEAP classification ($P < 0.001$), operative time ($P < 0.001$), laser device type ($P < 0.001$), length of the treated vein ($P < 0.001$), linear endovenous energy density ($P < 0.001$), and tumescent local anesthesia volume ($P < 0.001$) differed significantly. Pain after EVLA was significantly more frequent in the nonphlebectomy group than in the phlebectomy group ($P = 0.005$). During follow-up, 34 of 954 limbs (3.6%) underwent additional sclerotherapy for residual visible varicose veins after EVLA. No statistical difference was found in the rate of additional sclerotherapy between the groups ($P = 0.849$). Logistic regression showed that female sex (odds ratio [OR], 6.18; 95% confidence interval [CI], 1.86−20.6; $P = 0.003$) is significantly associated with additional sclerotherapy, and concomitant phlebectomy is not a significant predictor of additional sclerotherapy (OR, 0.844; 95% CI, 0.375−1.90; $P = 0.682$).

Conclusions: Patient preference for additional sclerotherapy was comparable between those who underwent EVLA with and without concomitant phlebectomy. This result supports our present strategy of avoiding simultaneous phlebectomy at the time of primary EVLA.

Endovenous laser ablation (EVLA), a minimally invasive treatment for varicose veins of the lower limbs, has become a well-established procedure in Japan since it was covered by the national health insurance in 2011. Owing to its advantages, such as high initial occlusion rate, minimal complications, and low recurrence rate, EVLA has increasingly become a replacement for conventional surgery, namely, saphenous vein stripping combined with phlebectomy.

Conflict of Interest: None to declare.

[1]*Division of Vascular Surgery, Department of Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan.*

[2]*Nagoya Vascular Surgery Clinic, Nagoya, Japan.*

Correspondence to: Yohei Kawai, MD, Division of Vascular Surgery, Department of Surgery, Nagoya University Graduate School of Medicine, 65 Tsurumai-cho, Showa-ku, Nagoya, Aichi, Japan; E-mail: yohei.bump@gmail.com

Ann Vasc Surg 2020; 66: 344–350
https://doi.org/10.1016/j.avsg.2019.12.025

Manuscript received: December 6, 2019; manuscript accepted: December 30, 2019; published online: 7 January 2020

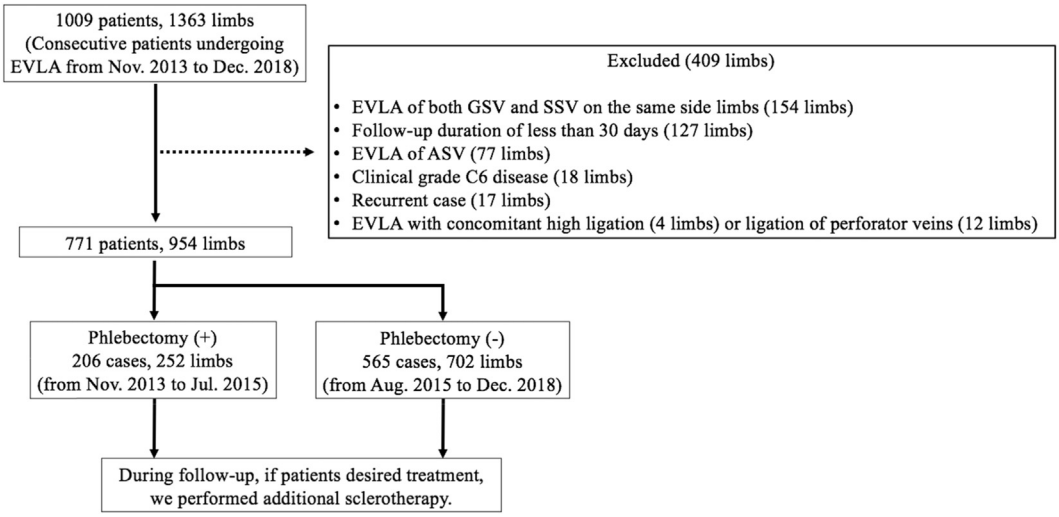

Fig. 1. Study flowchart. We included 954 limbs in 771 patients who underwent EVLA. From November 2013 to July 2015, we performed EVLA with concomitant phlebectomy. Starting in August 2015, we performed EVLA without phlebectomy. During follow-up, if patients desired treatment for residual visible varicose veins, we performed additional sclerotherapy. EVLA, endovenous laser ablation; GSV, great saphenous vein; SSV, short saphenous vein; ASV, accessory saphenous vein.

Because current clinical practice guidelines recommend ablation for the treatment of superficial venous insufficiency and phlebectomy or sclerotherapy for varicosities,[1,2] EVLA with concomitant phlebectomy is often performed in many institutions. However, phlebectomy is associated with cosmetic complications such as surgical scarring, hemorrhage, and hematoma. Several studies have evaluated whether varicose veins should be treated at the time of primary EVLA, but the results are equivocal.[3–11] The purpose of this single-center retrospective study was to compare the needs for additional sclerotherapy during follow-up after EVLA with and without concomitant phlebectomy.

METHODS

Study Population

This clinical investigation compared surgical characteristics and outcomes of 771 patients with symptomatic primary varicose veins due to reflux in the great saphenous vein (GSV) or small saphenous vein (SSV) who underwent EVLA at Nagoya Vascular Surgery Clinic from November 2013 to December 2018. Patients meeting any of the following criteria were excluded: EVLA of both GSV and SSV on the same side, follow-up duration of less than 30 days, EVLA of the accessory saphenous vein, clinical grade class (C) 6 disease, recurrent case, EVLA with concomitant high ligation, or ligation of perforator veins (Fig. 1).

Data were collected from a prospectively registered database. Patient records underwent careful retrospective review. This study was conducted in accordance with the Declaration of Helsinki. The Institutional Review Board of Nagoya University School of Medicine approved this study. All patients provided written informed consent before intervention and data collection.

Procedures and Follow-up

Before surgical treatment, the course of the saphenous vein to be treated was marked on the skin using ultrasonography with the patient standing in an upright position. After patients were put into a supine, prone, or reverse Trendelenburg position, local anesthesia with 1% lidocaine was given under ultrasonography guidance before the saphenous vein was punctured. A sheath was inserted into the target vein over a guide wire. A 980-nm bare-tip or 1,470-nm radial-tip laser catheter (ELVeS™ laser, Biolitec Inc., Germany) was inserted via the sheath. The laser catheter was advanced to the proximal end of the GSV or SSV under ultrasound visualization. A tumescent local anesthesia (TLA) solution (500 mL of saline and 40 mL of 1% lidocaine with epinephrine) was injected into the saphenous compartment. After the patient was placed in the Trendelenburg position, the catheter

Table I. Demographic and surgical characteristics

Variable	Phlebectomy (+)	Phlebectomy (−)	*P* value
Number of patients (limbs)	206 (252)	565 (702)	
Age (years)	61.7 ± 12.2	62.3 ± 13.5	0.521
Female sex	137 (66.5)	373 (66.1)	0.968
Height (cm)	159.7 ± 11.9	160.6 ± 9.0	0.250
Weight (kg)	59.2 ± 13.3	59.3 ± 12.1	0.872
Body mass index (kg/m^2)	23.0 ± 5.0	22.9 ± 3.8	0.835
Smoking	64 (31.1)	172 (30.4)	0.969
Treated vein			0.059
GSV	219 (86.9)	571 (81.3)	
SSV	33 (13.1)	131 (18.7)	
CEAP classification			<0.001
C2	37 (14.7)	161 (22.9)	
C3	155 (61.5)	329 (46.9)	
C4	57 (22.6)	202 (28.8)	
C5	3 (1.2)	10 (1.4)	
Vein diameter (mm)	6.8 ± 1.7	7.0 ± 3.1	0.182
Operative time (min)	32 [27−40]	24 [19−31]	<0.001
Device			<0.001
980 nm	64 (25.4)	0	
1,470 nm	188 (74.6)	702 (100)	
Length of treated vein (cm)	28.1 ± 10.3	36.7 ± 12.2	<0.001
LEED (J/cm)	84.0 ± 14.9	55.1 ± 13.7	<0.001
Volume of TLA (mL)	440 ± 99	342 ± 150	<0.001
Number of incisions	4.7 ± 2.3		

Data are presented as mean ± standard deviation, median [interquartile range], and number (%).
GSV, great saphenous vein; SSV, short saphenous vein; LEED, linear endovenous energy density; TLA, tumescent local anesthesia.

was slowly drawn back while compressing the limb along the saphenous vein. Over the time period of the study, our strategy for treating varicose veins changed. From November 2013 to July 2015, we performed concomitant phlebectomy for varicose veins except in patients who had CEAP C6 disease. Since August 2015, we have performed EVLA without phlebectomy.

During phlebectomy, stab avulsion was performed with a 1−2 mm incision and a hook after ablation treatment. Incisions were closed using a Steri-Strip (3M, St. Paul, MN).

After the procedure, the treatment site was dressed with gauze. Patients wore compression stockings (20 mm Hg). The gauze was removed on the day after surgery. The patients were instructed to wear the compression stockings for 2 weeks after surgery. Postoperative follow-up included visits at 2 days, 1 month, and 1 year after treatment. At the aforementioned time points, we performed physical examination to assess procedure-related complications such as pain, skin burn, and hematoma. Ultrasonography was also performed to identify occlusion, recanalization, endovenous heat-induced thrombosis (EHIT), and deep vein thrombosis (DVT).

If patients desired treatment for residual visible varicose veins during follow-up after the primary procedure, we performed additional sclerotherapy. Two 2.5-mL syringes were filled with 0.5 mL of 1% polidocanol and 2 mL of air using the Tessari method.[12] The reagent was immediately injected after preparation to occlude the residual superficial varicose veins. Compressive stockings were used for 1 month.

Clinical Endpoint

The endpoint of this study was the need for additional sclerotherapy after EVLA. The endpoint was compared among patients who underwent EVLA with and without concomitant phlebectomy to identify predictors for sclerotherapy after EVLA.

Statistical Analysis

Normally distributed continuous variables were expressed as means ± standard deviation (SD). Medians and interquartile ranges (IQRs) were presented for other continuous variables. Categorical variables were presented as percentages.

Statistical significance was calculated and compared between the two groups using the χ^2

Table II. Complications after endovenous laser ablation

Variable	Phlebectomy (+) $n = 252$	Phlebectomy (−) $n = 702$	*P* value
Pain, number of limbs	12 (4.8)	78 (11.1)	0.005
Hematoma, number of limbs	67 (26.6)	163 (23.2)	0.324
EHIT			0.305
Class 1	11	17	
Class 2	10	26	
Class 3	1	6	
Class 4	0	0	
DVT	0	0	N/A

Data are presented as numbers (%).
EHIT, endovenous heat-induced thrombosis; DVT, deep vein thrombosis; N/A, not applicable.

Table III. Postoperative data

Variable	Phlebectomy (+) $n = 252$	Phlebectomy (−) $n = 702$	*P* value
Follow-up (months)	12.3 [11.6−13.2]	12.2 [2.1−13.7]	0.156
Recanalization	4 (1.6)	25 (3.6)	0.176
Additional sclerotherapy	8 (3.2)	26 (3.7)	0.849

Data are presented as median [interquartile range] and numbers (%).
EVLA, endovenous laser ablation; GSV, great saphenous vein.

test or unpaired *t*-test as appropriate. Logistic regression and Cox regression were used to assess the association between each variable and simultaneous phlebectomy and additional sclerotherapy. *P* values less than 0.05 were considered statistically significant. All statistical analyses were performed using IBM Statistics Statistical Package for Social Science (SPSS), version 24 (IBM Corporation, Armonk, NY).

RESULTS

During the study period, 1,363 limbs underwent EVLA at our institution, but 409 limbs were excluded based on the exclusion criteria. Consequently, 954 limbs were retrospectively analyzed (Fig. 1). Of the 954 limbs included in the present study, 252 limbs underwent simultaneous phlebectomy (26.4%; phlebectomy group) and 702 limbs did not (73.6%; nonphlebectomy group).

Baseline and Surgical Characteristics

The baseline and surgical characteristics of both groups are shown in Table I. In the univariate analysis, the following variables were significantly different: CEAP classification, operative time, laser device type, length of the treated vein, linear endovenous energy density (LEED), and TLA volume.

Complications After EVLA

There were no statistical differences in the frequency of hematoma, EHIT, or DVT. However, pain after EVLA was significantly more frequent in the nonphlebectomy group than in the phlebectomy group (4.8% vs. 11.1%, $P = 0.005$) (Table II).

Follow-Up Outcomes

During a median follow-up of 12.3 months (IQR, 11.6−13.2 months) in the phlebectomy group and 12.2 months (IQR, 2.1−13.7 months) in the nonphlebectomy group, recanalization occurred in 4 (1.6%) and 25 limbs (3.6%), respectively.

Additional sclerotherapy after EVLA for residual visible varicose veins was performed in 8 limbs (3.2%) in the phlebectomy group and 26 limbs (3.7%) in the nonphlebectomy group. No statistical differences were observed between the groups (Table III).

Predictors of Additional Sclerotherapy after EVLA

Univariate analysis revealed that women were more likely to undergo additional sclerotherapy ($P = 0.003$) (Table IV). Logistic regression showed that female sex (odds ratio [OR], 6.18; 95%

Table IV. Univariate analysis of preoperative and postoperative characteristics of patients or limbs with or without additional sclerotherapy after endovenous laser ablation

Variable	Sclerotherapy (+) $n = 34$	Sclerotherapy (−) $n = 920$	P value
Age (years)	60.3 ± 12.4	62.7 ± 12.9	0.291
Female sex	31 (91.2)	600 (65.2)	0.003
Body mass index (kg/m2)	23.5 ± 3.5	22.9 ± 4.0	0.421
Smoking	3 (8.8)	233 (25.3)	0.084
Treated vein			
GSV	28 (82.3)	762 (82.2)	0.968
CEAP classification			0.102
C2	9 (26.5)	189 (20.6)	
C3	20 (58.8)	464 (50.4)	
C4	4 (11.8)	255 (27.7)	
C5	1 (2.9)	12 (1.3)	
Preoperative vein diameter (mm)	7.1 ± 2.2	7.0 ± 2.8	0.851
Device			
1,470 nm	32 (94.1)	857 (93.2)	0.843
Length of treated vein (cm)	31.6 ± 13.1	34.5 ± 12.3	0.174
Phlebectomy	8 (23.5)	244 (26.5)	0.844

confidence interval [CI], 1.86−20.6; $P = 0.003$) was significantly associated with additional sclerotherapy after EVLA. However, concomitant phlebectomy (OR, 0.844; 95% CI 0.375−1.90; $P = 0.682$) was not a significant predictor of additional sclerotherapy (Table V).

DISCUSSION

The goal of the conventional surgical treatment for symptomatic varicose veins due to GSV or SSV insufficiency was to eliminate venous hypertension in the GSV or SSV and reduce the appearance of visible varicosities by phlebectomy, which usually required spinal or general anesthesia.[13−15] In 2001, Navarro et al.[16] introduced EVLA as an alternative to conventional surgery that was suitable for day-surgery settings.[17] Since it became covered by the national health insurance in 2011 in Japan, this method has become widely used because it can be performed under local anesthesia, does not require an incision scar, and enables patients to walk soon after the procedure.

Some researchers have reported that concomitant phlebectomy with EVLA reduces the need for staged procedures and improves quality of life (QoL).[4,5] El-Sheikha et al.[18] have indicated that concomitant phlebectomy of varicosities is associated with optimal improvement in both clinical disease severity and QoL. In fact, surgeons at many institutions perform EVLA with concomitant phlebectomy for varicose veins. In contrast, others have insisted that EVLA without concomitant phlebectomy is preferable because it might reduce the need for adjunctive procedures through natural regression of varicose tributaries.[7−9]

In the early days, we performed concomitant removal of varicose veins as thoroughly as possible at the time of EVLA. When patients desired treatment for residual visible varicose veins during follow-up, we performed additional sclerotherapy. However, we have changed our usual protocol to perform EVLA without simultaneous phlebectomy and additional sclerotherapy if needed, considering that concomitant phlebectomy is associated with issues such as incision scars, nerve damage, hemorrhage, and hematoma.

Although several studies have supported this staged strategy for varicose veins,[4−6,10,11] previous studies are equivocal, as previously mentioned. Therefore, we compared results after EVLA with or without simultaneous phlebectomy. This is the first report of real-world experience with additional sclerotherapy after EVLA with versus without concomitant phlebectomy.

In our study, we observed no significant difference in the rate of additional sclerotherapy between the phlebectomy and nonphlebectomy groups. This is partly because our EVLA procedure has changed because of our expertise. At the beginning of this study, when we observed tortuosity in the target saphenous vein, we performed EVLA from the saphenofemoral junction or saphenopopliteal junction to the proximity of the tortuosity without ablating the tortuous segment. Over the course of this study, however, we began to

Table V. Multivariate analysis of predictors of additional sclerotherapy after endovenous laser ablation

	Additional sclerotherapy after EVLA		
Predictor	OR	95% CI	*P* value
Age (years)	0.978	0.953−1.00	0.088
Female sex	6.18	1.86−20.6	0.003
Phlebectomy	0.844	0.375−1.90	0.682

Data are presented as means ± standard deviation and numbers (%).
GSV, great saphenous vein; EVLA, endovenous laser ablation; OR, odds ratio; CI, confidence interval.

cannulate the sheath as distally as possible by using a 0.035 guidewire and to treat the GSV or SSV for as long as possible, including the tortuous segment. As shown in Table I, there was a significant difference in the length of the treated vein between the groups. As previously reported, treating a longer length of the saphenous vein could lead to better outcomes.[19−21] It was possible that treating longer segments might have avoided residual major tributary reflux leading to recurrent varicosities.

This increase in the length of ablation also resulted in a significant difference in LEED. We used 10W for both the 980 nm and 1,470 nm systems in the continuous mode. We started the ablation with higher LEED and decreased it stepwise through the knee where the vein is more superficial. Therefore, in our recent cases with longer ablation, mean LEED seems to be lower than our early cases.

We also observed a significant difference in CEAP classification (Table I). This result was an accidental event because this study basically included all-comers, and we did not change our indications for EVLA during the study period. Although patients with severe symptoms (C4 and C5) represented a higher proportion of the treated patients in the later period than the earlier period, we did not observe a significant difference in the proportion of patients who underwent additional sclerotherapy between the groups. This finding also suggests that our recent strategy could have achieved patient satisfaction even in clinically severe cases.

When we performed simultaneous phlebectomy, we used TLA as local anesthesia. This resulted in a significantly higher volume of TLA used and significantly fewer patients who had pain in the phlebectomy group.

Multivariable analysis showed that female sex is the only predictor of additional sclerotherapy after EVLA. We think that women might pay more careful attention to the physical appearance of residual varicose veins. Phlebectomy was not associated with staged sclerotherapy.

Limitations of the present study should be mentioned. First, this was a retrospective study performed by a single vascular surgery institution. Second, although our study is one of the largest case series compared with previous reports,[4−11] median follow-up was approximately 1 year, which might have been too short to identify the clinical impact of concomitant phlebectomy. Third, we did not use measures of QoL such as the Aberdeen Varicose Vein Questionnaire and venous clinical severity score after the procedure. In this study, we performed additional sclerotherapy only based on patient request, not [on] objective findings. Therefore, although some patients could have prominent residual varicose veins, additional sclerotherapy was not performed if they were satisfied with the initial treatment.

CONCLUSIONS

Our study demonstrated that concomitant phlebectomy has no significant impact on the desire for additional sclerotherapy during follow-up after EVLA. Female sex was a significant predictor of future sclerotherapy after EVLA. These results validated our present strategy of performing EVLA and avoiding simultaneous phlebectomy.

REFERENCES

1. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2011;53:2S−48S.
2. Gloviczki P, Gloviczki ML. Guidelines for the management of varicose veins. Phlebology 2012;27(Suppl 1):2−9.
3. Hager ES, Ozvath KJ, Dillavou ED. Evidence summary of combined saphenous ablation and treatment of varicosities versus staged phlebectomy. J Vasc Surg Venous Lymphat Disord 2017;5:134−7.
4. Lane TR, Kelleher D, Shepherd AC, et al. Ambulatory varicosity avulsion later or synchronized (AVULS): a randomized clinical trial. Ann Surg 2015;261:654−61.
5. Carradice D, Mekako AI, Hatfield J, et al. Randomized clinical trial of concomitant or sequential phlebectomy after

endovenous laser therapy for varicose veins. Br J Surg 2009;96:369–75.
6. Theivacumar NS, Dellagrammaticas D, Mavor AI, et al. Endovenous laser ablation: does standard above-knee great saphenous vein ablation provide optimum results in patients with both above- and below-knee reflux? A randomized controlled trial. J Vasc Surg 2008;48:173–8.
7. Monahan DL. Can phlebectomy be deferred in the treatment of varicose veins? J Vasc Surg 2005;42:1145–9.
8. Schanzer H. Endovenous ablation plus microphlebectomy/sclerotherapy for the treatment of varicose veins: single or two-stage procedure? Vasc Endovascular Surg 2010;44:545–9.
9. Welch HJ. Endovenous ablation of the great saphenous vein may avert phlebectomy for branch varicose veins. J Vasc Surg 2006;44:601–5.
10. Harlander-Locke M, Jimenez JC, Lawrence PF, et al. Endovenous ablation with concomitant phlebectomy is a safe and effective method of treatment for symptomatic patients with axial reflux and large incompetent tributaries. J Vasc Surg 2013;58:166–72.
11. Obi AT, Reames BN, Rook TJ, et al. Outcomes associated with ablation compared to combined ablation and transilluminated powered phlebectomy in the treatment of venous varicosities. Phlebology 2016;31:618–24.
12. Tessari L, Cavezzi A, Frullini A. Preliminary experience with a new sclerosing foam in the treatment of varicose veins. Dermatol Surg 2001;27:58–60.
13. Mayo CH. Treatment of varicose veins. Surg Gynecol Obstet 1906;2:385–8.
14. Homans J. The operative treatment of varicose veins and ulcers, based upon a classification of these lesions. Surg Gynecol Obstet 1916;22:143–58.
15. Myers TT. Results and technique of stripping operation for varicose veins. JAMA 1957;163:89–92.
16. Navarro L, Min RJ, Boné C. Endovenous laser: a new minimally invasive method of treatment for varicose veins-preliminary observations using an 810 nm diode laser. Dermatol Surg 2001;27:117–22.
17. Arun O, Oc B, Duman A, et al. Endovenous laser ablation under general anesthesia for day surgery: feasibility and outcomes of the 300 patients. Ann Thorac Cardiovasc Surg 2014;20:55–60.
18. El-Sheikha S, Nandhra D, Carradice T, et al. Clinical outcomes and quality of life 5 years after a randomized trial of concomitant or sequential phlebectomy following endovenous laser ablation for varicose veins. Br J Surg 2014;101:1093–7.
19. Theivacumar NS, Dellagrammaticas D, Beale RJ, et al. Factors influencing the effectiveness of endovenous laser ablation (EVLA) in the treatment of great saphenous vein reflux. Eur J Vasc Endovasc Surg 2008;35:119–23.
20. Theivacumar NS, Darwood R, Gough MJ, et al. Neovascularisation and recurrence 2 years after varicose vein treatment for sapheno-femoral and great saphenous vein reflux: a comparison of surgery and endovenous laser ablation. Eur J Vasc Endovasc Surg 2009;38:203–7.
21. Shoab S, Lowry D, Tiwari A. Effect of treated length in endovenous laser ablation of great saphenous vein on early outcomes. J Vasc Surg Venous Lymphat Disord 2016;4:416–21.