Closed randomized comparative study of great saphenous vein crossectomy laser ablation versus standard laser technique to minimize recurrence in the treatment of primary varicose veins

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Background

Incompetence at the saphenofemoral junction (SF) is the most common cause (70%) of varicose veins. Endovenous laser ablation (EVLA) uses laser energy to ablate incompetent axial veins selectively and was originally described for the treatment of GSV reflux and its related varicosities. The venous system is a network of interconnected vessels; any preserved inflow of the saphenous-femoral mouth can cause postoperative recurrence. However, according to the literature, the greatest risk of recurrence is associated with the stump of the GSV of venous tributaries, including great venous trunks parallel to the GSV in the thigh.

Aim of the work

Comparison of the standard endovenous laser ablation technique (1.5–2 cm from SFJ) versus crossectomy ablation for the treatment of varicose veins regarding recurrence of reflux and incidence of endovenous heat-induced thrombus (EHIT) in the first week.

Patients and methods

In all, 80 patients admitted to Ain Shams University Hospitals and Alexandria Armed Forces Hospital from Jan. 1st, 2021 to Jan. 30th, 2023 participated in the study. The patients were divided evenly into two groups:

Participants were randomly assigned to one of the trial groups using the sealed envelope method.Group A was treated by ablation of the great saphenous vein at the saphenofemoral junction (0 cm from SFJ) using 1470 nm radial double-ring diode laser fibers (ELVeS Radial 2ring^{TM} fiber) and Biolitec Ceralas E1470/15 W laser machine. Group B was treated by ablation of the great saphenous vein at 1.5–2 cm from the saphenofemoral junction using the same laser fiber and machine. Ablation was done after putting an appropriate amount of tumescent anesthesia (500 mg lidocaine, 1 mg of epinephrine, and 12.5 mEq sodium bicarbonate added to a 1-liter solution of 0.9% normal saline). The ultrasound machine was used for the accurate placement of the laser fiber. Postoperative duplex was done on day 1, 1 week, and at 6, 12, and 18 months.

Results

Mean age: 39.28+/– 12.27 years in both groups; M/F: 23/17 in the first group, 20/20 in the second group. Postoperative duplex showed the absence of reflux in both groups after 1 day, after 6 months. One patient (2.5%) in group A and four patients (10%) in group B showed recurrent reflux, while recurrent refluxes were observed in one case (2.5%) in group A and five cases (12.5%) in the other group after 12 and 18 months of follow-up. One patient (2.5%) developed superficial thrombophlebitis along the course of the ablated great saphenous vein in both groups while extension to the deep veins was not detected in both groups.

Conclusion

Crossectomy (ablation at 0 cm at SFJ) ablation of varicose veins with 1470 radial double rings and nm diode laser with an appropriate amount of tumescent showed better results with less recurrence rate due to neovascularization or tributaries left than the standard technique of endovenous laser ablation of varicose veins (1.5–2 CM from SFJ). Along with showing a lesser incidence of thermal propagation into the deep system (EHIT) both crossectomy and standard techniques showed the same complication rate regarding venous thrombosis.

Keywords:
crossectomy, laser ablation, varicose veins

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Introduction

Chronic venous insufficiency is a major problem that includes varicose veins as one of its entities. Most of the patients need intervention to deal with the problem at a specific stage of the disease [1]. Incompetence at the saphenofemoral junction (SFJ) is the most common cause (70%) of varicose veins. (Fig. 1).

Endovenous ablation of varicose veins is the new era for managing varicose veins with clinical success comparable to the conventional stripping operations that were adopted; however, the recurrence from the neovascularization from the stump is the main problem facing standard laser ablation [2].

In the standard technique, we used to stay 2 cm away from the SFJ to minimize the possibility of laser propagation into the deep system (CFV) and to treat the incompetence of the SFJ and the GSV instead of surgical removal of the vein as was adopted in the surgical approach [3]. So, if we minimize the remnant of the vein, this will minimize the ambulatory venous hypertension causing less complaints of the limb affected with better outcomes [4].

In recent research, the authors detected that one of the causes of recurrence is the tributaries in the upper 2 cm of the GSV without ablation that were previously ligated in the surgical removal of varicose veins. So, when we go up for a crossectomy we minimize the tributaries left open as a source of reflux and recurrence of varicose veins [5].

Some studies were discussing the role of superficial epigastric vein sparing with the permanence of a functionally draining saphenous stump in reducing the incidence of varicose vein recurrence. Superficial epigastric veins are part of a descending pathway useful to drain the portal vein system and inferior abdominal veins in pathological conditions (e.g., liver cirrhosis), and thus closure of the superficial epigastric vein can stimulate an intense proliferation of vessels to guarantee venous drainage of this part of the body to common femoral veins [6].

We believe that crossectomy (ablation at 0 cm at SFJ, exactly at the level of the origin of the superficial external epigastric vein) ablation of varicose veins with 1470 radial double rings, diode laser with an appropriate amount of tumescent along with accurate positioning of the laser fiber under ultrasonography guidance won't allow thermal propagation into the deep venous system, getting better results with less recurrence rate due to neovascularization or tributaries left and no difference in complication rates will occur [7].

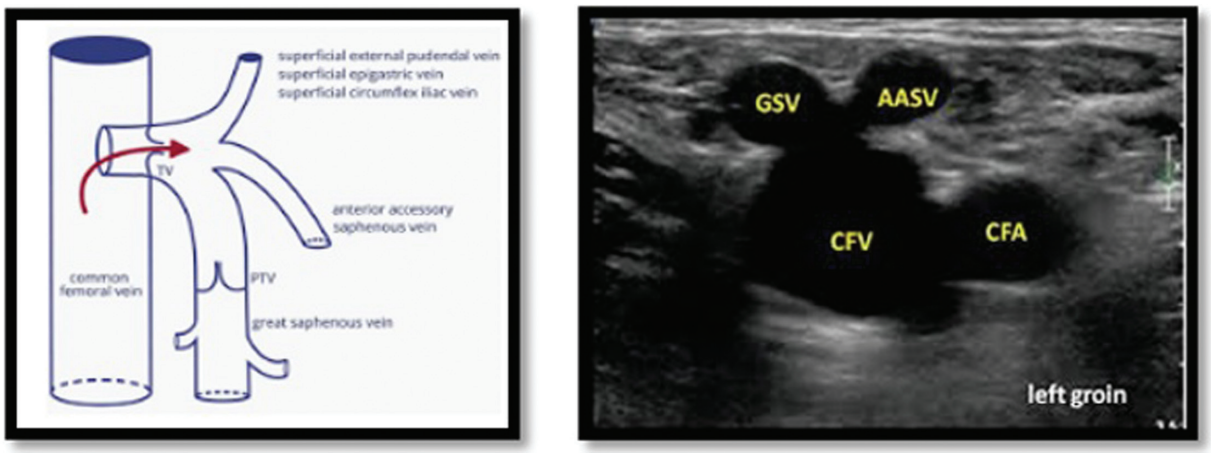
Objective

Comparison of the standard endovenous laser ablation (1.5–2 cm from SFJ) technique versus crossectomy ablation for the treatment of varicose veins regarding recurrence of reflux and incidence of endovenous heat-induced thrombus (EHIT) in the first week.

Patients and methods

In all, 80 patients of primary varicose veins with great saphenous vein and saphenofemoral junction incompetence were admitted to Ain Shams University Hospitals and Alexandria Armed Forces Hospital from Jan. 1st, 2021 to Jan. 30th, 2023.

Figure 1



Reflux in the anterior accessory saphenous vein (AASV) and the (GSV).

Anterior accessory saphenous vein reflux patients were excluded from the study.

Patients were divided evenly into two groups:

Participants were randomly assigned to one of the trial groups using the sealed envelope method:

(1) Group A treated by ablation of the great saphenous vein at the saphenofemoral junction (0 cm from SFJ) (Fig. 2).
(2) Group B treated by ablation of the great saphenous vein at 1.5–2 cm from the saphenofemoral junction.

We used 1470 nm radial double rings diode laser fibers (ELVeS Radial 2ring™ fiber), and Biolitec Ceralas E1470/15 W laser machine to ablate the GSV in both groups. (Fig. 3).

Figure 2

Laser fiber at the SFJ.

Ablation was done after putting an appropriate amount of tumescent anesthesia (500 mg lidocaine, 1 mg of epinephrine, and 12.5 mEq sodium bicarbonate added to a 1-liter solution of 0.9% normal saline). The ultrasound machine was used for the accurate placement of the laser fiber.

Postoperative duplex was done on day 1, 1 week, and at 6, 12, 18 months.

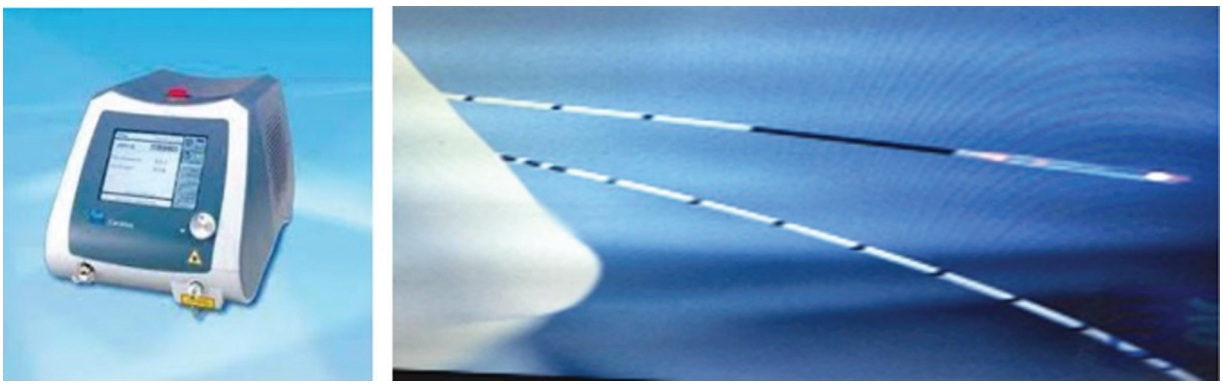
Results

Incompetence at the saphenofemoral junction (SFJ) is the most common cause (70%) of varicose veins. In this study, the age of the patients ranged from 28 to 44 years and 25 to 50 years in both groups with a mean age of 38.78±12.3 & 39.78±12.39 years, respectively. Male to female ratio was 20:20 and 23:17. The mean height and weight of the study participants was 1.73 (±0.09) meters and 91.74±10.3) kilograms, respectively, while the mean BMI was 30.8 ±3.03. Most of the participants were nonsmokers (61.25%) with only 38.75% smokers. Half of the participants underwent the standard procedure, while the other half underwent crossectomy. (Table 1).

Table 1 BMI and Smoking

	Mean±SDN (%)
Height in m	1.73±0.09
Weight in kg	91.74±10.3
Body mass index	30.8±3.03
Smoker	
No	49 (61.25%)
Yes	31 (38.75%)
Procedure	
Standard	40 (50%)
Crossectomy	40 (50%)

Figure 3



(Biolitec Ceralas laser machine) and (ELVeS Radial 2ring™ fiber.

In both groups, 63.75% of the study participants had the left side affected. About 96.25% of the participants had pain and heaviness, 65% had unsightness, 66.25% had dilated veins, and only 23.75% had edema. (Table 2).

The clinical assessment showed that these patients were related to C2-6. (Table 3).

Preoperative duplex examination revealed the incompetence of GSV and the GSV diameter that ranged from (4–12 mm) to (5–14 mm.) (Table 4).

Preoperative leg diameters (midway between the tibial tuberosity and the ankle joint) were 36.6 and 35.6 CM in both groups, which significantly dropped to 33.2 and 33.3 CM, while the preoperative thigh diameters (midway between the anterior superior iliac spine and the knee joint) were 48.01 & 46.3, which also dropped significantly to 43.9 and 43.5 CM postoperatively. (Table 5).

The postoperative prognosis of all patients is shown in the table and it can be seen that more than half of the participants (58.75%) took 2 days to return to work, while 36.25% took 3 days and only 5% took a day. Only 40% of the participants got ecchymosis immediately postoperatively. Two participants got postoperative superficial thrombophlebitis (STP), one in each group (2.5%) and no postoperative wound infection had been recorded (Table 6).

Immediate absence of reflux at the SFJ was observed in all patients (Fig. 4) that persisted in one-week follow-up. Recurrence of reflux was observed in the standard technique group after 6 months in four patients and in one more patient after 12 months and no more recurrence in 18 months. In the crossectomy technique group, only one patient had recurrence after 6 months, while no more recurrence patients were observed in 12 and 18 months.

No forward propagation of energy was observed during the ablation procedure in both technique groups and no deep venous thrombosis occurred in all patients (Fig. 5).

The overall recurrence of reflux in both groups was detected in six patients after 18 months of follow-up. In the standard technique group, neovascularization was observed in one patient (2.5%) as blue and red around a previously ablated saphenofemoral junction of a patient with recurrent varicosities on color duplex ultrasonography (Fig. 6), while developing incompetent perforators were shown in two patients (5%), and appearance of the incompetent anterior saphenous vein in one patient (2.5%) in the same group. Recanalization of the GSV was shown in one

Table 2 Clinical presentations

	N (%)
Side affected	
Left	51 (63.75%)
Right	29 (36.25%)
Heaviness	
No	3 (3.75%)
Yes	77 (96.25%)
Unsightness	
No	28 (35%)
Yes	52 (65%)
Dilated veins	
No	27 (33.75%)
Yes	53 (66.25%)
Edema	
No	61 (76.25%)
Yes	19 (23.75%)

Table 3 Clinical presentation of the patients in groups A and B

Clinical Presentation	A	B
C2	6 patients	2 patients
C3	14 patients	16 patients
C4	15 patients	20 patients
C5	5 patients	2 patients

Table 4 GSV diameter in groups A and B

Vein	A	B
GSV	Range: 4-12 mm	Range: 5–14 mm

Table 5 Pre- and postoperative lower regional limb diameters

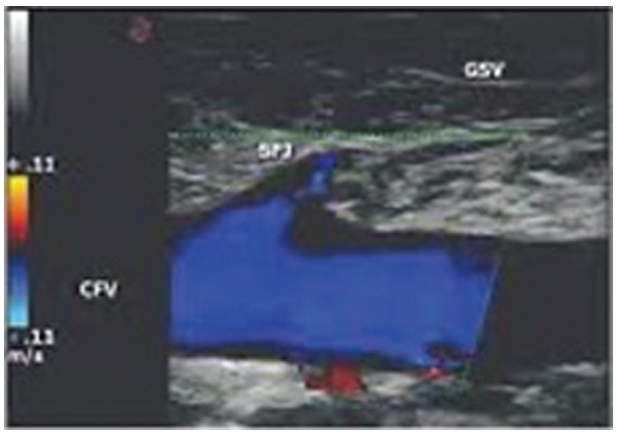
	Groups				
	Standard	Crossectomy	Test of Significance		
	Mean±SD. *N* (%)	Mean±SD. *N* (%)	Value	*P* value	Significance
Preoperative circumference of the leg	36.6±7.45	35.68±7.53	***t***= 0.552	0.582	NS
Postoperative circumference of the leg	33.25±7.42	33.3±7.37	***t***= 0.475	0.467	**S**
Preoperative circumference of the thigh	48.15±8.84	46.35±9.33	***t***= 0.886	0.378	NS
Postoperative circumference of the thigh	43.98±8.49	43.5±9.29	***t***= 0.441	0.461	**S**

patient (2.5%) in the crossectomy group as the cause of the recurrence of varicose veins. (Table 7).

Table 6 Patient prognosis

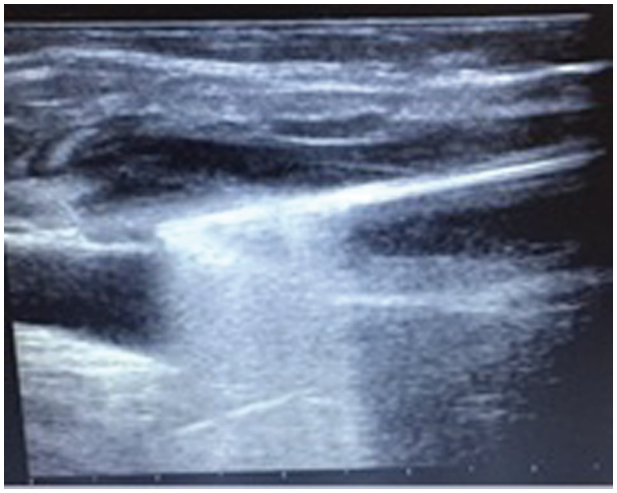
	N (%)
Time to return to work (in days)	
1.00	4 (5%)
2.00	47 (58.75%)
3.00	29 (36.25%)
Ecchymosis (immediate post-op)	
No	48 (60%)
Yes	32 (40%)
STP (immediate post-op)	
2 patients	2.5 (%)
Infection	
0	0
Recurrence after 2 years	
6 patients	6/80 (7.5%)

Figure 4



Absent postoperative venous reflux (duplex examination).

Figure 5



Energy propagation during venous ablation of GSV.

No major complications were detected in patients of both groups in the postoperative period including deep vein thrombosis, burn, and neurological problems.

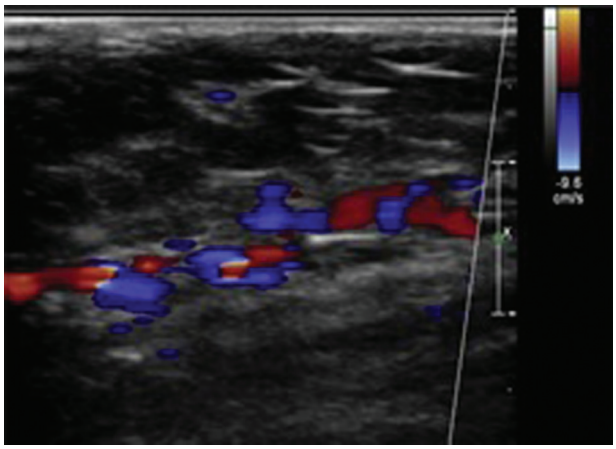
Discussion

Symptomatic varicose veins are considered a burden over the normal lifestyle of patients. Intervention to minimize varicose vein complications is advised and this goes with the recommendation of the Society of Vascular Surgery [8].

Endovenous ablation of varicose veins is the new era for managing varicose veins with clinical success comparable to the conventional stripping operations that were adopted; however, the recurrence from the neovascularization from the stump is the main problem facing standard laser ablation [2].

In this study, we compared the standard endovenous laser ablation (1.5–2 CM. from SFJ) technique versus crossectomy ablation for the treatment of varicose veins. Male to female ratio was 2:1, and this matches the results of Marlin W. Schul *et al.* who mentioned that they had no significant difference in demographic distribution in their 65 patients [9], while James Laredo *et al.* had female predominance in their 35 patients with a ratio of 1:6 [10].

Figure 6



Postoperative neovascularization of the GSV stump right groin.

Table 7 Causes of recurrence

Cause of recurrence	Standard technique	Crossectomy technique
Neovascularization	One patient (2.5%)	0
Incompetent tributaries	Two patients (5%)	0
Incompetent anterior saphenous vein	One patient (2.5%)	0
recanalization	One patient (2.5%)	One patient

The study showed two groups that were divided between crossectomy and the standard laser ablation technique of varicose veins. Immediate absence of reflux at the SFJ was observed in all patients that persisted in 1 week follow-up; recurrence of reflux was observed in four patients (10%) of the standard technique group after 6 months, one more patient (2.5%) after 1 year and 18 months, while only one patient (2.5%) after 6, 12, and 18 months in the crossectomy technique group, and this goes with almost 90% success after 2 years by Recek et al. [4].

We reached a follow-up period of 18 months, and this was higher than with Gibson *et al.* who had a follow-up of only 6 months in the crossectomy technique [8].

Neovascularization occurred in only one limb (2.5%) after the standard technique, which was also observed by Thomas et al. [11]. In our study, we found one participant (2.5%) who developed recurrent varicose veins due to the development of incompetent anterior saphenous vein in the standard technique group.

Also, recanalization of the GSV in one patient (2.5%) in both groups as a cause of recurrence, and this differed from the results shown by Thomas *et al.*, which claimed recanalization as the most common cause of varicose veins in their study sample of 86 limbs of 43 patients of bilateral incompetent great saphenous vein varices followed by the development of anterior accessory saphenous vein incompetence. [11] In contrast to other reports, incompetent calf-perforating veins were an infrequent cause of recurrence [12,13]. Several studies have reported new incompetence of the AASV to be responsible for the recurrence of varicose veins in 8%–35% of cases [14,15].

Regarding thrombotic events postoperatively, we did not report any cases of DVT in both groups and only one patient (2.5%) of STP in the standard group, and according to Hartmann *et al.* they included 16,398 patients who underwent endovenous thermal ablation of GSV and their DVT percentage was 1.7%. Thrombotic events post GSV endovenous thermal ablation were infrequent events and comparable to our results with the difference in the included sample size [3].

Further studies are needed to show whether endovenous laser ablation of GSV flush at SFJ (0 cm), sometimes called laser crossectomy or preventive ablation of a non-refluxing AASV would reduce the number of recurrences from the groin and in particular involvement of the AASV [16] and reducing the incidence of neovascularization post-EVLA [17].

Future perspectives

We need to increase the sample size of our study with a longer follow-up period of up to 4 or 5 years to show the efficacy of the crossectomy technique in the management of great saphenous vein primary varicose veins.

Conclusion

Crossectomy (ablation at 0 cm at SFJ) ablation of varicose veins with 1470 nm radial double rings diode laser with an appropriate amount of tumescent showed better results with less recurrence rate due to neovascularization or tributaries left than the standard technique of endovenous laser ablation of varicose veins (1.5–2 CM from SFJ). Along with showing a lesser incidence of thermal propagation into the deep system (EHIT) both crossectomy and standard techniques showed the same complication rate regarding venous thrombosis.

Acknowledgements

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Conflicts of interest

No conflict of interest.

References

1 Piazza G. Varicose veins. Circulation 2014; 130:582–7.

2 Hartmann K. Endovenous (minimally invasive) procedures for treatment of varicose veins: The gentle and effective alternative to high ligation and stripping operations. Hautarzt 2020; 71:12–9.

3 Al Samaraee A, McCallum IJD, Mudawi A. Endovenous therapy of varicose veins: A better outcome than standrd surgery?. Surgeon 2009; 7:181-6. Available from: http://dx.doi.org/10.1016/S1479-666X(09)80043-7

4 Recek C. Significance of Reflux Abolition at the Saphenofemoral Junction in Connection with Stripping and Ablative Methods. Int J Angiol. 2015;24: 249–261.

5 Anwar MA, Idrees M, Aswini M, Theivacumar NS. Fate of the tributaries of sapheno femoral junction following endovenous thermal ablation of incompetent axial vein – A review article. Phlebology 2019; 34:151–5.

6 Özpak B, Ilhan G. ACTA PHLEBOL. EDIZIONI MINERVA MEDICA. Acta Phlebologica. 2014;15:117–21.

7 Hirokawa M, Ogawa T, Sugawara H, Shokoku S, Sato S. Comparison of 1470 nm laser and radial 2ring fiber with 980nm laser and bare-tip fiber in endovenous laser ablation of saphenous varicose veins: a multicenter, prospective, randomized, non-blind study. Ann Vasc Dis 2015; 8:282–9.

8 Gibson K, Khilnani N, Schul M. American College of Phlebology Guidelines – Treatment of refluxing accessory saphenous veins. Treating refluxing anterior accessory vein 2017; 32:448–52.

9 Schul MW, Vayuvegula S, Keaton TJ, Park O, Lafayette W. The clinical relevance of anterior accessory great saphenous vein re fl ux. J Vasc Surg 2020; 8:1014–20. Available from:

10 Laredo BYJ, Lee BB, Neville RF. Endovenous Thermal Ablation of the Anterior Accessory. 2010; (March)

11 O'Donnell TF, Balk EM, Dermody M. Recurrence of varicose veins after endovenous ablation of the great saphenous vein in randomized trials. J Vasc Surg: Venous and Lym Dis 2016; 4:97–105.

12 Brake M, Chung LS, Amanda SC, Shalhoub J, Davies AH. Pathogenesis and etiology of recurrent varicose veins. J Vasc Surg 2013; 57:860–8.

13 Anwar MA, Idrees M, Aswini M, Theivacumar NS. Fate of the tributaries of saphenofemoral junction following endovenous thermal ablation of incompetent axial vein – a review article. Phlebology 2019; 34:151–155.

14 Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, Cullum N, *et al.* A randomized trial of early endovenous ablation in venous ulceration. N Engl J Med 2018; 378:2105–14.

15 O'Donnell TF, Balk EM, Dermody M, Tangney E, Iafrati MD. Recurrence of varicose veins after endovenous ablation of the great saphenous vein in randomized trials. J Vasc Surg Venous Lymphat Disord 2016; 4:97-105. Available from: http://dx.doi.org/10.1016/j.jvsv.2014.11.004

16 Winokur RS, Khilnani NM, Min RJ. Recurrence patterns after endovenous laser treatment of saphenous vein reflux. Phlebology 2016; 31:496–500.

17 Labropoulos N, Bhatti A, Leon L, Borge M, Rodriguez H, Kalman P. Neovascularization after great saphenous vein ablation. Eur J Vasc Endovasc Surg 2006; 31:219–222.