

CONCOMITANT ENDOVENOUS LASER ABLATION AND FOAM SCLEROTHERAPY IN TREATMENT OF LOWER LIMBS VARICOSE VEINS

By

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ABSTRACT

Background: Endovenous laser ablation (EVLA) is a well-established alternative to surgery in the treatment of truncal and perforating vein insufficiency. After the refluxing truncal or perforating vein is ablated, the remaining varicosities are removed with phlebectomy or alternatively treated with sclerotherapy. Sclerotherapy is traditionally performed with liquid agents, but foam sclerotherapy is becoming more popular. EVLA and concomitant ultrasound (US)-guided foam sclerotherapy are recent treatment methods alternative to surgery in the treatment of Lower Limbs Varicose Veins.

Objective: To evaluate safety and efficacy of Concomitant endo venous LASER ablation of truncal veins and foam sclerotherapy in extratruncal veins in treatment of lower limbs varicose veins.

Patients and Methods: This prospective randomized controlled study was conducted in the vascular surgery department at Al-Azhar university hospital-Damietta, in the period from september 2019 to May 2021 (20 months). The study included 50 patients, males were 22(44%) while females were 28(56%), Presented by primary varicose veins. In these 50 patients (60 legs; (bilateral in 10 patients), the incompetent veins were great saphenous vein, small saphenous vein, perforating veins, and a combination of these. In all patients, after EVLA of the incompetent veins, foam sclerotherapy of extra truncal veins was performed for the remaining varicosities. We use foam sclerotherapy by lauromacrogol 400 (polidocanol) 3% by direct puncture or duplex guided.

Results: Endovenous laser ablation was technically successful in all cases. Concomitant direct puncture foam sclerotherapy was also technically successful in all cases. During the follow-up, recanalization of the laser-ablated refluxing veins occurred in (8 %) and was treated with repeat EVLA or ultrasound-guided foam sclerotherapy (USGFS). Major complications occurred in 1-2 % of the treated legs and included skin necrosis and calf vein thrombosis.

Conclusions: Endovenous laser ablation and concomitant foam sclerotherapy is feasible and effective. The procedures are associated with a low complication rate and can be performed in both legs in the same session. Concomitant use of laser and foam may potentially decrease the recanalization rate of laser-ablated vessels.

Keywords: Endovenous LASER, Ablation and Foam Sclerotherapy, Lower Limbs Varicose Veins.

INTRODUCTION

Varicose veins are one of the most common vascular problems that appear in a large portion of population. The disease

affects about 10-40% of 30-70 years old people. Most studies have suggested varicose veins are more common in women, with a female to male ratio 3:1

(*DePopas & Brown 2018 and Sharma et al., 2019*).

Varicose veins are the veins which permanently lost its valvular efficiency and as a result of continuous dilatation under pressure, in the course of time become elongated, tortuous and pouched (*Khan and Ahmed 2019*).

The greater incidence of left sided varicose veins that has been reported by some may be related to left common iliac vein compression because the venous return from the leg is always partially impeded where the right common iliac vein in front of the sacral promontory (*Yang et al., 2018*).

Truncal varicosities mean that the patient has poor functioning valves and dilatation of one or more of the truncal veins, the great saphenous vein and the small saphenous vein (*Garcia and Labropoulos, 2018*).

Varicose veins constitute a progressive disease, except after pregnancy and delivery. During its course the disease produces complications that usually prompt the patient to seek medical care. The most frequent complications are superficial thrombophlebitis, acute bleeding, eczema, and skin ulceration (*Janugade et al., 2017*).

The standard treatment of varicose veins for many years surgical ligation and stripping of the affected vein. Although outcomes have improved in recent years because of enhanced understanding of lower extremity venous anatomy, the recurrence rate with this approach is frequently reported to be between 20% and 30% (*Allegra et al., 2017*).

The most notable endovenous advancements are the new widespread techniques of radiofrequency ablation (RFA) and endovenous LASER ablation (ELA). These methods may be demonstrated clinical superiority to stripping and surgical ligation as well as significantly less postoperative pain and recovery time (*Theivacumar et al., 2018*).

The thermal energy generates heat and steam bubbles within the lumen of the target vessel, destroying the endothelial lining of the vessel. This causes an inflammatory reaction resulting in a thrombotic occlusion that effectively closes off the vein and eventually leads to fibrosis (*Mazayshvili and Akimov, 2018*).

Endo venous LASER ablation is considered safe and efficacious and recommended for the treatment of saphenous reflux. Foam sclerotherapy is recommended for the treatment of telangiectasias, reticular veins and extra truncal varicose veins. The use of endovenous LASER ablation may be recommended over the use of foam sclerotherapy for the treatment of truncal reflux (*Shi et al., 2015*).

Sclerotherapy can be used to treat a different size of veins, although it is most commonly used to treat smaller vessels such as the reticular veins and telangiectasias. Sclerotherapy is best defined as the introduction of a chemical into the lumen of a vein to induce endothelial damage that results in thrombosis and eventually fibrosis (*Parlar et al., 2015*).

The Aim of the present study was to evaluate safety and efficacy of Concomitant endo venous LASER ablation of truncal veins and foam

sclerotherapy in extratruncal veins in treatment of lower limbs varicose veins.

PATIENTS AND METHODS

This prospective randomized controlled study was conducted in the vascular surgery department at Al-Azhar University Hospital-Damietta, in the period from September 2019 to May 2021 (20 months). The study included 50 patients, males were 22(44%) while females were 28(56%), Presented by primary varicose veins.

Their mean age was 30.60 ± 7.559 years “ranging from 20-52 years” all patients were belonging to class C2-6EpAs & pPr according to clinical-etiology-anatomy-pathophysiology (CEAP) classifications. This means:

- C₂= clinically stage II venous disease in which there is uncomplicated moderate to severe varicosities.
- C₆= clinically stage VI venous disease in which there is unhealed venous ulcer.
- Ep= etiologically the disease was primary with well-functioning deep system.
- As =anatomically the varicosities affected the superficial system “mainly the great & small saphenous veins” and perforators.
- Pr = pathologically the disease was refluxing in nature.

Inclusion criteria:

Patient presented with unilateral or bilateral lower limb varicose veins complaining of one or more of the following:

- Leg pain secondary to varicose veins.

- Cosmetic disfigurement of lower limb due to varicose veins.
- Leg ulcer, itching or pigmentation of lower limb due to varicose veins
- Incompetent sapheno femoral and/ or sapheno popliteal junctions.

Exclusion criteria:

- Secondary lower limb varicose veins.
- Lower limb lymphedema
- Recurrent varicose veins of lower limb
- Tortuous GSV rendering the vein unsuitable for endovenous treatment
- Acute superficial thrombophlebitis of lower limb.
- Congenital anomalies of venous system of lower limb.
- Lower limb ischemia.
- Lower limb malignancy.
- History of sclerosing drugs hypersensitivity.

All patients were subjected to the following:

- a. Clinical evaluation.
- b. Duplex assessment.

Clinical evaluation was carried out for all patients according to the following scheme:

- Detailed history (disfigurement, pain, bleeding, deep venous thrombosis, drug allergy, anticoagulant therapy,.....).
- Detailed general examinations.
- Lower limb examination to detect:
 1. Distribution of veins affected.
 2. Incompetent perforators.

3. Shape (spider, serpentine or saccular).

Duplex was done as a routine to all patients to detect:

- Patency of the deep venous system.
- Sapheno-femoral or sapheno-popliteal reflux.
- Presence and number of perforators.
- Diameter of GSV and distance from the skin.
- Exclude any venous anomalies of L.L.
- Exclude accessory GSV & mapping of it if present.
- Mapping of superficial venous system of L.L.

Medical treatment:

Anti-inflammatory drugs was advised post-operative for 3 days, prophylactic anti-coagulant was prescribed for 1 day. Topical and systemic Steroid was prescribed to patients with local hypersensitivity to foam sclerotherapy.

Every patient was advised to:

Avoid straining; strenuous physical activity or Valsalva maneuvers for the first month because they may contribute to

early recanalization. Avoid prolonged car or plane travel of more than 4 hours during the first month after treatment to decrease the incidence of the thromboembolic events.

All patients were reviewed for occurrence of complication:

Systemic complications: (plumonyary embolism – drug reaction - transient cofusional status – visual disturbance), and **local complications:** (DVT, phlebitis, skin pigmentation, skin necrosis).

Follow up and assessments:

The patients were examined at the time of randomization, and after 1week, 1 month, 3 months and 6months. Clinical and duplex examination was performed, and determines the diameter of the GSV 3 cm below the sapheno-femoral junction was measured.

Criteria for technical success were closed or absent GSV flow. A recanalized GSV or treatment failure was defined as an open part of the treated vein segment more than 10 cm in length. Complications were regarded as minor if they required no therapy, and major if they required treatment, admission to hospital, or led to permanent adverse sequelae or death.

RESULTS

The age ranged from 20-52 years with mean value 30.60 ± 7.559 years. Male cases were 22(44%) while female cases were 28(56%) and about 29(58%) were from urban place and 21(42%) were from rural place. The comorbidity in our study, there are 4(8%) diabetic patients, 10(20%) dyslipidemic patients and no one has hypertension (HTN).

The CEAP of the studied group that 6(12%) their limbs classified as C2,

23(46%) their limbs classified as C3, 10(20%) their limbs classified as C4, 7(14%) their limbs classified as C5 and 4(8%) their limbs classified as C6.

Doppler US of the studied group show that 45(90%) Doppler US findings show ISFJ and perforators and 5(10%) Doppler US findings show ISPJ and perforator. Also, perforators of the studied group show that 30(60%) had in leg, 11(22%)

had in thigh and 9(18%) had in thigh and leg together.

We had minimal accepted complications post operatively, 12(24%) had skin pigmentation, 10(20%) had ecchymosis, 4(8%) had effect on healing of venous ulcer, 4(8%) had Saphenous

venire analyzation after six months, 3(6%) had Burn, 2(4%) had Skin ulceration and 1(2%) had deep vein thrombosis (DVT).

The number of days to return to daily activity of the studied group and it was ranged from 4-10 days with mean value 7.10 ± 1.876 days (Table 1).

Table (1): Distribution of studied sample according to patient’s demographic data, comorbidity, limbs classified according to the CEAP, Doppler US, complications and return to daily activity

Parameters	Number	Percent
Age (years)		
≤30	30	60.0
>30	20	40.0
Range	20-52	
Mean±S.D.	30.60±7.559	
Gender		
Male	28	56.0
Female	22	44.0
Comorbidity		
DM	4	8.0
HTN	0	0
Dyslipidemia	10	20.0
Limbs classified according to the CEAP		
C2	6	12.0
C3	23	46.0
C4	10	20.0
C5	7	14.0
C6	4	8.0
Doppler US		
ISFJ and perforator	45	90.0
ISPJ and perforator	5	10.0
Complications		
Skin pigmentation	12	24.0
Ecchymosis	10	20.0
Effect on healing of venous ulcer	4	8.0
Saphenous veni recanalization after six months	4	8.0
Burn	3	6.0
Skin ulceration	2	4.0
Deep vein thrombosis (DVT)	1	2.0
Return to daily activity		
≤5	15	30.0
>5	35	70.0
Range	4-10	
Mean±S.D.	7.10±1.876	

The GSV diameter results of the studied group show that GSV diameter was ranged between 4.50 – 9.50 with a mean value of 6.52 ± 1.271 and it was decreased significantly at postoperative time to reach after 6 months of follow up to be at mean value 0.52 ± 0.252 .

The SSV diameter results of the studied group show that SSV diameter was ranged between 4.00 – 7.00 with a mean value of 5.50 ± 1.158 and it was decreased significantly at postoperative time to reach after 6 months of follow up to be at mean value 0.63 ± 0.153 (Table 2).

Table (2): Evaluation of GSV and SSV diameter pre and post operatively after LASER ablation

GSV Diameter	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
Min. – Max.	4.50 – 9.50	3.20 – 8.50	1.30 – 6.40	0.60 – 4.30	0.10 – 0.90
Mean \pm S.D.	6.52 ± 1.271	5.31 ± 1.273	3.50 ± 1.070	1.88 ± 0.731	0.52 ± 0.252
P		<0.001	<0.001	<0.001	<0.001
S.S.V. Diameter (n=5)	Preoperative	1 week	1 month	3 months	6 months
Min. – Max.	4.00 – 7.00	3.20 – 6.20	1.20 – 4.30	0.60 – 2.20	0.50 – 0.80
Mean \pm S.D.	5.50 ± 1.158	4.20 ± 1.296	2.66 ± 1.141	1.26 ± 0.581	0.63 ± 0.153
P		0.005	0.003	<0.001	0.025

DISCUSSION

In truncal and perforating vein insufficiency, the traditional method to treat remaining varicosities after ELA is ambulatory phlebectomy.

Although excellent cosmetic results can be obtained in experienced hands, ambulatory phlebectomy has some drawbacks. First, it is a surgical procedure that requires special surgical instruments, which is not suitable in the office setting. Second, it is a time-consuming treatment, and most interventional radiologists are not familiar with this technique. Third, although large varicose veins can be successfully removed small reticular and spider veins remain after ambulatory phlebectomy, and these veins require treatment with sclerotherapy. Fourth, some patients do not like the idea that their veins are being removed with hooks (Fernaández *et al.*, 2018).

Thus, until recently, the only option for such varicose veins has been ambulatory phlebectomy. In the last decade, foam sclerotherapy was introduced and has become popular. Foam sclerotherapy has some advantages over liquid sclerotherapy. First, because the liquid mixes instantly with blood, its concentration drops and its ablative effect diminishes rapidly. Instead, foam pushes the blood rather than mixing with it and it thus may retain its concentration over a long distance in the vein lumen. As a result, its ablative effect is several times stronger than the liquid, and for this reason, it is suitable for the treatment of even large varicose veins. Second, because it is mixed with air, it contains fewer drugs, but it becomes more effective (King *et al.*, 2017).

Although successfully used in truncal and perforating vein ablation instead of endovenous laser or radiofrequency, foam

sclerotherapy is most commonly preferred in the treatment of pelvic–gonadal vein insufficiency and for the ablation of remaining varicosities after EVLA of truncal and perforating veins (*Coleridge Smith, 2011*).

In the literature, we could find only two studies reporting the results of concomitant use of foam sclerotherapy after endovenous ablation (*Park et al., 2016* and *King et al., 2017*).

In both, the combined treatment was associated with a high success rate (98–100% closure of the refluxing veins) and a low complication rate. Similarly, during the 1–20 month follow-up, there was only 8% recanalization of the refluxing veins in our study. This compares favorably with the 3–12% recanalization rates reported in the literature (*Proebstle et al., 2018*).

In our study, we observed patient's perforators in leg (60%), (22%) in thigh and (18%) in both leg and thigh after the successful treatment with combined EVLA and Foam sclerotherapy, although the refluxing perforating veins were still closed. This phenomenon was also observed in 16–22% of the patients after ligation and stripping of the incompetent GSV and found independent from the proximal GSV as well from Insufficient perforating veins (*Van Neer et al., 2019*).

In our study, with a detailed color Doppler US examination, showed that (90%) doppler US findings show (ISFJ and perforators) and (10%) doppler US findings show (ISPJ and perforators). Regardless of their origin, these remaining varicose veins were successfully treated with foam sclerotherapy in our study, as in others in the literature (*Theivacumar et al., 2018*).

Both persistent reflux and recanalization of the laser-treated veins were generally observed at late (3 and 6 months) follow-up in our study, which is also the observation. We believe, therefore, that a Doppler US control at 3–6 months should be routinely performed in such patients to detect recanalization and persistent varicose veins (*Vuylsteke et al., 2016*).

In our study, we saw some minor complications hyperpigmentation, ecchymosis, burn, skin ulceration and telangiectatic matting (due to foam sclerotherapy), which mostly resolved within few days (without treatment), and transient paresthesia (due to EVLA), which mostly resolved within few weeks (with neuro tonics). Also skin ulceration was observed, which may be due to foam extravasation. All except one of the necrotic wounds healed within 4 weeks, although systemic and topical antibiotics were necessary. Calf vein thrombosis was seen in at least one of the crural veins.

The rate of deep vein thrombosis (DVT) after EVLA has been reported to be 0–5.7% in the literature. Although theoretically the risk of DVT is expected to increase with concomitant foam sclerotherapy, we had one patient complicated by DVT (2%) may be due to small sample and was (1%) in (*King et al., 2017*).

Also, we did some measures to reduce the risk of DVT. First, instead of injecting a large volume of foam via a single puncture, we injected small volumes via multiple punctures. Second, when we saw filling of the varicose veins with foam, we stopped the injection at that site and continued the injection via another

puncture. Third, we always performed foam sclerotherapy after all EVLAs were finished, and we made the patient walk for 20 min immediately after the procedure. Fourth we give single dose prophylactic anti-coagulant after the procedure. Fifth, we instructed the patient to be active (walking or performing foot exercises) for at least 1-2 h (daily) after discharging the patient.

In our experience, concomitant use of Foam sclerotherapy with EVLA provides some advantages.

First, because the refluxing vein and the varicosities are treated in the same session, the total duration and also the cost of the treatment are reduced, because sterile materials used in EVLA (e.g., injectors, stopcocks) can also be used for the Foam sclerotherapy, and the amount of foam is reduced because the large varicose veins become smaller after tumescent anesthesia

Second, the period spent in compression stockings is shorter after combined EVLA and Foam sclerotherapy compared with the separate treatment, which is preferred by the patient. Third, if the varicose veins are left untreated after EVLA, they may be thrombosed as a result of stagnation.

This may complicate or interfere with the subsequent sclerotherapy (or phlebectomy) and may require anticoagulant treatment. Foam sclerotherapy performed shortly after EVLA prevents this complication.

Fourth, passage of the foam from the varicosities into the laser-ablated refluxing truncal or perforating veins creates an

additional ablation, and this may result in a more durable occlusion.

CONCLUSION

Endovenous laser ablation and concomitant foam sclerotherapy is feasible and effective. The procedures are associated with a low complication rate and can be performed in both legs in the same session. Concomitant use of laser and foam may potentially decrease the recanalization rate of laser-ablated vessels.

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إقتران العلاج التداخلي بالليزر والحقن الرغوي التصليبي فى علاج دوالي الطرفين السفليين

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خلفية البحث: تعرف دوالي الساقين بأنها تمدد وتعرج الأوردة السطحية بالطرف السفلي وتنتج عن عدم كفاءة الصمامات بالأوردة المصابة مما يترتب عليه ارتجاع الدم وزيادة الضغط داخل الوريد. وتتفاقم هذه الزيادة في الضغط خاصة إذا ما صاحبها عدم كفاءة في صمامات الأوردة العميقة. يعتبر إستئصال الوريد بالليزر بديلاً راسخاً للجراحة في علاج قصور الوريد الجذعي والانتقابي. بعد إستئصال الوريد الجذعي أو المثقب، تتم إزالة الدوالي المتبقية بإستئصال الوريد أو علاجها بالتصليب. يتم إجراء المعالجة بالتصليب بشكل تقليدي باستخدام عوامل سائلة، ولكن العلاج بالتصليب الرغوي أصبح أكثر شيوعاً.

الهدف من البحث: تقييم سلامة وفعالية إستئصال الأوردة الجذعية بالليزر المصاحب وفعالية العلاج التصليبي الرغوي فى الأوردة الخارجية فى علاج دوالي الأطراف السفلية.

المرضى وطرق البحث: أجريت هذه الدراسة العشوائية المرتقبة فى قسم جراحة الأوعية الدموية بمستشفى جامعة الأزهر بدمياط فى الفترة من سبتمبر 2019 إلى مايو 2021 (20 شهراً). اشتملت الدراسة على 50 مريضاً، 22 (44%) من الذكور والإناث 28 (56%)، قدمها الدوالي الأولية. فى هؤلاء المرضى الخمسين (60 رجلاً)؛ (ثنائية فى 10 مرضى)، كانت الأوردة غير الكفوّة عبارة عن وريد صافن كبير، وريد صافن صغير، وأوردة مثقوبة، ومزيج من هذه الأوردة. تم إجراء المعالجة المصلبة للأوردة الجذعية الزائدة للدوالي المتبقية، ونستخدم العلاج التصليبي الرغوي بواسطة 3% (polidocanol) 400 lauromacrogol عن طريق ثقب مباشر أو توجيه مزدوج.

نتائج البحث: كان إستئصال الوريد بالليزر ناجحًا تقنيًا في جميع الحالات. وكان العلاج التصليبي الرغوي المصاحب للثقب المباشر ناجحًا تقنيًا في جميع الحالات. وأثناء المتابعة حدثت إعادة إستئناء الأوردة الراجعة التي تم إستئصالها بالليزر في (8%) وتم علاجها بإستئصال الوريد بالليزر المتكرر أو العلاج التصليبي الرغوي الموجة بالموجات فوق الصوتية. حدثت مضاعفات كبيرة في 1-2% من الساقين المعالجة بما في ذلك نخر الجلد وجلطة في الوريد.

الاستنتاج: إستئصال الوريد بالليزر وما يصاحب ذلك من العلاج التصليبي الرغوي ممكن وفعال. ترتبط الإجراءات بمعدل مضاعفات منخفض ويمكن إجراؤها في كلا الساقين في نفس الجلسة. قد يؤدي الإستخدام المتزامن لليزر والرغوة إلى تقليل معدل إعادة الاستئناء للأوعية التي يتم إستئصالها بالليزر.

الكلمات الدالة: الليزر داخل الوريد، الحقن الرغوي التصليبي، دولي الأطراف السفلية.