

Ten-year clinical and instrumental results of endovenous laser ablation of great saphenous vein

G. BOTTA

Aim. The aim of this paper was to assess the clinical experience and 10-year-instrumental results of varicose veins treated with endovenous laser ablation (EVLA) of great saphenous vein.

Methods. From December 2001 to February 2005 167 patients (126 F e 41 M), affected by varicose veins due to incompetence of great saphenous vein (GSV) detected by Duplex ultrasound scanning (DUS), were treated with EVLA at our Center. EVLA was performed at the beginning of our experience using in 66 patients an 810-nm diode laser (Diomed, NJ, USA). After January 2004 a 980-nm diode laser (Team laser, Padua, Italy) has been used in the other 101 patients.

Results. We recorded no intraprocedural complications. We detected at 24-hours clinical follow-up 29 cases (17%) of bruising of the thigh rapidly disappeared after a few days. 25 patients (15%) showed light pain at the treated lower limb appeared 3-4 days after the procedure lasted more than a week. At 1, 6 and 12 months DUS control the GSV obliteration was observed in 154/164 patients (94%). At 3-years follow-up the GSV was successfully occluded in 139/151 patients (92%), while at 5-years follow-up the same was occluded in 102/118 patients (86%). At 10-years instrumental follow-up we detected 11/110 cases (10%) of the GSV recanalization and 5/110 patients (4,5%) with recurrent varicose veins in the lower limb operated.

Conclusion. The EVLA represents a safe and effective technique for the correction of GSV reflux and it can be seen as good alternative to traditional surgery, especially if we respect the right indications. Our experience has shown, looking at the long-term results, that the endovascular obliteration of GSV presented excellent results, comparable with traditional open surgery.

KEY WORDS: Veins - Surgery - Laser therapy.

The standard treatment performed previously for varicose veins caused by incompetence of the

*Phlebological Unit
Department of General Surgery
University of Siena, Siena, Italy*

great saphenous vein (GSV) was the high ligation and stripping. Minimally invasive techniques have been developed within the last few years as an alternative to surgery in an attempt to reduce morbidity and improve recovery time. Endovenous laser ablation (EVLA) is one of the most promising of these new techniques and numerous studies have since demonstrated that it is safe and efficacious at long time. EVLA relies on thermal injury to promote occlusion of the vein and is successful in 88% to 100%¹⁻⁴ of treated limbs. Several wavelengths have been proposed, respectively 810, 980, 1064, 1320 and recently 1470 nm.^{5,6} The energy is administered endovenously, either in a pulsed fashion with fiber pullback in 3 mm increments every second or continuously with a constant pullback of the laser fiber at a velocity of 3 mm/s. At these settings, the average linear endovenous energy density (LEED), that is commonly used to report the dose administered to the vein, is between 80 and 120 j/cm.⁷ These dose induces heating of the vein wall, which is necessary to cause collagen contraction and destruction of endothelium. This stimulates vein wall thickening, leading to luminal contraction, venous thrombosis, and vein fibrosis.⁸ The discomfort felt by patients occurs 5 to 8 days after the procedure and is related to the inflammation resulting from successful endovenous ablation.⁹ When the laser procedure is properly performed, clinical outcome is excellent and the post-procedural DUS shows the complete obliteration of the saphenous trunk, with the disappearance

Corresponding author: G. Botta, Phlebological Unit of Siena Hospital, Department of General Surgery, University of Siena, Siena, Italy. E-mail giuseppe.botta@unisi.it

of the treated saphenous vein in the follow-up ultrasound controls.¹⁰

The purpose of this paper is to report our experience in the clinical and instrumental 10-year follow-up results of endovenous laser ablation in the treatment of patients with primary varicose veins of the lower limbs, hemodynamically supported by a reflux of the saphenous trunk.

Materials and methods

This study was designed as a single-center experience. From December 2001 to February 2005 167 patients, 126 females and 41 males, mean age 54 years, suffering from varicose veins caused by incompetence of the great saphenous vein, were treated with endovenous laser ablation at Phlebological Unit of Department of General Surgery of Siena Hospital.

Selection of the patients

History and physical examination was performed on the lower limbs of patients with varicose veins. All patients had symptomatic varicose veins and were classified according to the CEAP classification:¹¹ C2=89 patients, C3=41 patients, C4=9 patients, C5=5 patients, C6=6 patients. All patients were preoperatively studied with DUS and all examinations were performed in the same vascular laboratory: in 96 (73%) cases the saphenous trunk diameter, measured 5 cm under the sapheno-femoral junction (SFJ), was less than 10 mm, while in 35 (27%) cases we recorded a GSV dilatation more than 10 mm. After initial consultation and evaluation all patients gave written informed consent before the endovenous laser treatment.

The inclusion criteria of the study included:

a) varicose veins caused by insufficiency of saphenous femoral junction with GSV reflux >1 s relevant in stand-up position as demonstrated by duplex ultrasound imaging;

b) age at least 18 years;

c) ability to return for scheduled follow-up examinations after endovenous laser treatment.

The exclusion criteria included:

a) nonpalpable pedal pulses;

b) cardiovascular disease;

c) inability to ambulate;

d) general poor health;

e) pregnancy and nursing;

f) deep venous thrombosis;

g) extremely tortuous GSV that would not allow endovenous catheterization and passage of the laser fiber as identified on pretreatment venous DUS mapping.

EVLA procedure

All 167 EVLA procedures were performed in out-patients operating theater under loco-regional anesthesia, sometimes with obturator and femoral nerve block in order to perform the peripheral phlebectomy. In our study EVLA was performed at the beginning of our experience using in 66 patients an 810-nm diode laser (Diomed, Med pro Inc., NJ, USA). After March 2004 has been used in the other 101 patients a 980-nm diode laser (Team laser s.r.l., Padua, Italy). In 125 patients (75%) the GSV was exposed surgically by a small skin incision and in the other 42 patients (25%) the GSV was treated percutaneously under DUS control. The surgical/percutaneous access was the thigh in 87 cases (52%) and the proximal section of the leg in the other 80 cases (48%). EVLA kit containing a 600-micron bare-tip fiber with safety lock, a needle, a guide wire, and a 5-F sheath used to introduce the fiberoptic laser into the vein. The Seldinger technique guides the physician through a step-by-step process to complete the procedure safely and effectively as follows:

— the guide wire is introduced into the saphenous vein through a percutaneous puncture or an open venous cut-down;

— the 5-F sheath is then placed over the guide wire and advanced toward the sapheno-femoral junction (SFJ);

— using ultrasound guidance, the fiber-optic laser is then placed through the sheath and positioned 2 cm from the SFJ;

— once in place, the fiber-optic laser is then locked to the sheath;

— after confirming that the fiber-optic laser tip is at least 2 cm from the SFJ, the energy source is activated;

— the sheath, which is locked to the fiber-optic laser, is withdrawn at a specified speed to deliver the desired energy.

— In all patients was performed immediately after the procedure a compression bandage of the leg,

replaced a day later by a class II (23-32 mm Hg) compression stocking, which has been worn for 4 weeks.

Follow-up protocol

A clinical and instrumental examination was performed within 24 h of procedure and repeated at 1, 6, 12 months and then at 3, 5 e 10 year. The ultrasound examination, performed in the same vascular laboratory, measured the obliteration of treated trunk of GSV and any evidence of spontaneous recanalization or recurrent varicose veins.

Results

In our clinical experience we didn't register neither any kind of intraprocedural complication with endovenous laser ablation, nor collateral effects in treated patients. We detected at 24-hours clinical follow-up 29 cases (17%) of bruising of the thigh quickly disappeared after a few days. Twenty-five patients (15%) showed light pain at the lower treated limb appeared 3-4 days after the procedure lasted more than a week. **Only one patient** developed a focal thrombosis involving a GSV collateral. No DVT's were recorded during the follow-up. The resumption of daily activities took place a few hours after treatment and one week after all patients have resumed their normal activities and social work.

At 1 and 6 months DUS follow-up we recorded the complete obliteration of the treated GSV in 154/164 cases (94%), while in 8 patients (5%) the ultrasound control showed a GSV reperfusion. These patients underwent high ligation and stripping in 7 cases and EVLA procedure in the last one, with a good final result.

At 12-month follow-up we lost 4 patients and we detected only one case of asymptomatic reperfusion of GSV that showed a maximum diameter no more than 3 mm.

The complete obliteration of GSV was observed in 139/151 cases (92%) at DUS 3-years follow-up with 5 patients (3%) showing a GSV recanalization and 4 patients (3%) a varicose recurrence.

The 5-years DUS control showed an excellent result in 102/118 patients (86%) with complete disappearance of GSV in the thigh in 54 cases (46%) and

evidence of the saphenous trunk reduced to a thin fibrous cord, hyperechoic, with no endoluminal flow in 48 cases (41%). In 12 patients (10%) the saphenous trunk was found still open with evidence of SFJ reflux, however the maximum diameter of the GSV was less than 4 mm in all patients that were symptom-free. Only 4 patients (3%) developed recurrent varicose veins due to SFJ reflux.

At 10-years clinical and instrumental follow-up we detected 94/110 patients (85%) with complete obliteration of GSV, while in 11/110 cases (10%) the GSV recanalization was evident and 5/110 patients (5%) showed a recurrent varicose veins in the lower limb operated (Tables I, II).

Discussion

The primary aim in the treatment of saphenous vein insufficiency should be directed toward identification of the highest level of reflux and ablation of the incompetent venous segment.¹² Although the surgical ligation and stripping have been used successfully in the past, the current trend toward the endovenous laser ablation has shown that patients respond well to the procedure and that the incompetent venous sections can be treated readily.^{13, 14}

In the first our clinical experience was used a 810-nm diode laser,^{15, 16} because this wavelength is absorbed primarily by hemoglobin, which is the target chromophore responsible for the transformation of light energy into heat energy.

Then was used a 980-nm diode laser because this wavelength is absorbed by water and hemoglobin too, which gives the same power, but a greater thermic effect.^{17, 18}

Gerard¹⁹ and Oh²⁰ detailed their findings with the 980-nm diode laser. They found complete occlusion and retraction of the GSV over the postoperative period (4 and 12 weeks, respectively). Proebstle²¹ have shown that a 940-nm diode laser is effective in treating insufficiency of the saphenous vein, with a 6 month follow-up showing no recanalization of the vessel.

Looking at the eight failures of our experience, which occurred in the first phase of our experience during the learning curve of the procedure, led to the conclusion that in some cases had not been given the right indication, for example we treated patients with GSV diameter more than 15mm, otherwise an un-

correct laser energy administration, probably due to a too fast retraction of the fiber within the GSV.

Regarding the indications to EVLA,²² should be observed the following criteria:

- patients belonging to class 2 to 6 of the CEAP classification;
- deep venous system competence and patency;
- presence of GSV incompetence without tight tortuosity.
- absence of GSV dilatation up to 15 mm.
- absence of previous thrombophlebitis or previous GSV sclerotherapy.

It is very important, in order to minimize the complications,²³ to perform a correct DUS preoperative study in all patients undergoing EVLA. The DUS preoperative study can select the patients unfit for ELVT, who need a standard treatment of high ligation and stripping.

The five patients, who developed recurrent varicose vein at 10-years follow-up, had an undiagnosed anterior saphenous vein incompetence. In case of incompetence of GSV alone the EVLA treatment could be a good therapeutic option, otherwise in case of SFJ high incompetence with reflux >2 s, the standard high ligation and stripping seems to be the best surgical solution.

Another crucial point is the anatomical morphology of the SFJ. The presence of tight angulation does not allow the right positioning of the optical fiber and this may result in a too long stump, that could be responsible of a late GSV recanalization.

It is very important do not get to close at SFJ up to the epigastric vein with the probe in order to avoid DVT. In our series we had no cases of postoperative or long-term DVT.

The laser fiber can hole the vein wall and cause skin ecchymosis that represents the most common complications in our and many other series.

Another side effect is fairly frequent occurrence in the days following the treatment of pain due to an inflammatory process, that occurs as a result of thermal damage caused by the laser. But it was also suggested a more direct involvement of the saphenous nerve, damaged by heat, in the genesis of pain more often than is reported near the knee, where the nerve is close to the GSV wall.

The results are considered very good when the symptoms of chronic venous insufficiency improves and instrumental control shows the complete disappearance of the GSV trunk or at least its trans-

formation into a fibrous cord, hyperechoic, without lumen.

Unfortunately these results do not occur in all cases. In our experience at 10-years follow-up the GSV recanalization occurs in 10% of patients, even if they are symptom free, while bad results are evident in five patients, who have a symptomatic recurrence varicose veins.

Conclusions

In the last decades the radical criteria in the varicose veins therapy, based on removing of all dilated and refluxed veins subsequent at the traditional ablative methods, was widely discussed after the introduction of conservative surgical procedure, like Chiva, valvuloplasty, closure technique with radiofrequency.

The endovenous laser treatment of saphenous vein became part of this background. Its mini-invasivity with excellent aesthetic results, above all when we use the percutaneous access, the quick post-operative retake with immediate return to the normal activities, the possibility of ambulatory control, make it an innovative technique of great interest for the correction of saphenous reflux.

Nevertheless it open a space to wide discussion and consideration of hemodynamics type, if compared to the other kind of surgical correction.^{24, 25}

The upper collaterals at the crosse, remained opened, drain in the femoral common vein and it is possible to show with duplex scan far away from the treatment. Moreover the presence of a saphenous stump opened of 15-20 mm maximum length, seems to be in contrast with the surgical radical knowledge about groin crossotomy. Undoubtedly up to now we haven't sufficient elements to foresee the evolution of the long saphenous stump, recognized by all like one hinge element of the groin recurrence.

The primary failure and recurrence after EVLA around 10-15% at 10-year follow-up were non-significantly different compared with open surgery.^{26, 27} However they had lower haematoma, less wound infection, less pain and quicker return to normal activities.

Also the our experience has shown, looking at the long-term results, that the endovascular laser ablation presented good and comparable results with

traditional open surgery, especially if we respect the right indications to treatment.

Riassunto

Risultati clinici e strumentali a 10 anni dopo ablazione laser della grande safena

Obiettivo. Scopo del lavoro è stata la valutazione dell'esperienza clinica e dei risultati strumentali a 10 anni dopo trattamento dei pazienti varicosi con l'ablazione laser della grande safena (EVLA).

Metodi. Dal dicembre 2001 al febbraio 2005 167 pazienti (126 F e 41 M), affetti da vene varicose a causa dell'incompetenza della vena grande safena (GSV) documentata dall'ecocolor Doppler, sono stati trattati con EVLA. Questa procedura è stata effettuata all'inizio della nostra esperienza utilizzando in 66 pazienti un laser a diodi 810 nm (Diomed, NJ, USA). Dopo il mese di gennaio 2004 è stato utilizzato un laser a diodi 980 nm (Team Laser, Padova, Italia) negli altri 101 pazienti.

Risultati. Non è stata registrata nessuna complicazione intraprocedurale. Abbiamo rilevato al follow-up clinico dopo 24 ore 29 casi (17%) di ecchimosi della coscia rapidamente scomparse dopo pochi giorni. 25 pazienti (15%) hanno lamentato un lieve dolore lungo la vena trattata 3-4 giorni dopo la procedura. A 1, 6 e 12 mesi il controllo strumentale ha rilevato l'obliterazione della GSV in 154/164 pazienti (94%). A 3 anni di follow-up la GSV era completamente occlusa in 139/151 pazienti (92%), mentre al follow-up a 5 anni la stessa vena è apparsa occlusa in 102/118 pazienti (86%). Al follow-up strumentale a 10 anni abbiamo rilevato 11/110 casi (10%) di ricanalizzazione e 5/110 pazienti (4,5%) con vene varicose recidive nell'arto inferiore operato.

Conclusioni. L'ablazione laser della grande safena rappresenta una procedura sicura ed efficace per la correzione del reflusso della GSV e può essere visto come una buona alternativa alla chirurgia tradizionale, soprattutto se vengono rispettate le giuste indicazioni. La nostra esperienza ha mostrato, guardando i risultati a lungo termine, che l'obliterazione endovascolare della grande safena dà risultati eccellenti, paragonabili a quelli della chirurgia tradizionale.

PAROLE CHIAVE: Vene - Chirurgia - Laserterapia.

References

- Mundy L, Merlin TL, Fitridge RA, Hiller JE. Systematic review of endovenous laser treatment for varicose veins. *Br J Surg* 2005;92:1189-94.
- Min RJ, Zimmet SE, Isaacs MN, Forrestal MD. Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Interv Radiol* 2001;12:1167-71.
- 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.
- Pannier F, Rabe E. Mid-term results following endovenous laser ablation (EVLA) of saphenous veins with a 980 nm diode laser. *Int Angiol* 2008;27:475-81.
- Goldman MP, Mauricio M, Rao J. Intravascular 1320-nm laser closure of the great saphenous vein: a 6- to 12-month follow-up study. *Dermatol Surg* 2004;30:1380-5.
- Pannier F, Rabe E, Rits J, Kadiss A, Maurins U. Endovenous laser ablation of great saphenous veins using a 1470 nm diode laser and the radial fibre--follow-up after six months. *Phlebology* 2011;26:35-9.
- Proebstle TM, Kruppenauer F, Gul D, Knop J. Nonocclusion and early reopening of the great saphenous vein after endovenous laser treatment is fluence dependent. *Dermatol Surg* 2004;30:174-8.
- Weiss RA. Endovenous techniques for elimination of saphenous reflux: a valuable treatment modality. *Dermatol Surg* 2001;27:902-5.
- Sharif MA, Soong CV, Lau LL, Corvan R, Lee B, Hannon RJ. Endovenous laser treatment for long saphenous vein incompetence. *Br J Surg* 2006;93:831-5.
- Min RJ, Khilnami N, Zimmet S. Endovenous Laser Treatment of Saphenous Vein Reflux: Long-term results. *J Vasc Interv Radiol* 2003;14:991-6.
- Kistner RL, Eklof B, Masuda EM. Diagnosis of chronic venous disease of the lower extremities: the "CEAP" classification. *Mayo Clin Proc* 1996;71:338-45.
- Botta G. Terapia chirurgica delle varici. *Manuale di Flebologia - Esperienza della Scuola Senese*. Laris Editrice Colle di Val d'Elsa (SI) Italia, settembre 2009, pag 215-243.
- Agus GB, Mancini S, Magi G; IEWG. The first 1000 cases of Italian Endovenous-laser Working Group (IEWG). Rationale, and long-term outcomes for the 1999-2003 period. *Int Angiol* 2006;25:209-15.
- Botta G. Il trattamento laser endovenoso della malattia varicosa. *Acta Phlebologica* 2006;7(Suppl. 1 al 2):5.
- 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.
- Botta G, Berna F, Comandi A, Tommasino G, Mancini S. Il trattamento laser endovenoso della grande safena: quattro anni di esperienza. *Giornale degli Ospedali* 2007;3:45-50.
- Pannier F, Rabe E. Mid-term results following endovenous laser ablation (EVLA) of saphenous veins with a 980 nm diode laser. *Int Angiol* 2008;27:475-81.
- Samuel N, Wallace T, Carradice D, Smith G, Mazari F, Chetter I. Evolution of an endovenous laser ablation practice for varicose veins. *Phlebology* 2013;28:248-56.
- Gerard JL, Desgranges P, Bequemin JP, Desse H, Mellièrè D. Feasibility of ambulatory endovenous laser for the treatment of greater saphenous varicose veins: one-month outcome in a series of 20 patients. *J Mal Vasc* 2002;27:222-5.
- Oh C-K, Jung D-S, Jang H-S, Kwon K-S. Endovenous laser surgery of the incompetent greater saphenous vein with a 980-nm diode laser. *Dermatol Surg* 2003;29:1135-40.
- Proebstle TM, Gul D, Kargl A, Knop J. Endovenous laser treatment of the lesser saphenous vein with a 940-nm diode laser: early results. *Dermatol Surg* 2003;29:357-61.
- Botta G. Indicazioni, controindicazioni e complicanze del trattamento laser endovascolare. *Med Est* 2008;32:153-4.
- Malgor RD, Gasparis AP, Labropoulos N. Morbidity and Mortality after Thermal Venous Ablations. *Int Angiol* 2015 [epub ahead of print].
- Pan Y, Zhao J, Mei J, Shao M, Zhang J. Comparison of endovenous laser ablation and high ligation and stripping for varicose vein treatment: a meta-analysis. *Phlebology* 2014;29:109-19.

24. van den Bos RR, Malskat WS, De Maeseneer MG, de Roos KP, Groeneweg DA, Kockaert MA *et al.* Randomized clinical trial of endovenous laser ablation versus steam ablation (LAST trial) for great saphenous varicose veins. *Br J Surg* 2014;101:1077-83.
25. Samuel N, Carradice D, Wallace T, Mekako A, Hatfield J, Chetter I. Randomized clinical trial of endovenous laser ablation versus conventional surgery for small saphenous varicose veins. *Ann Surg* 2013;257:419-26.
26. Biemans AA, Kockaert M, Akkersdijk GP, van den Bos RR, de Maeseneer MG, Cuypers P *et al.* Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. *J Vasc Surg* 2013;58:727-34.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Received on March 31, 2015.

Accepted for publication on April 8, 2015.

PROOF
MINERVA MEDICA