

Outcomes and critical aspects of endovenous laser treatment in CVI. A perspective from IEWG

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On 2004 Michel Perrin published on *Phlébologie*, till 1st March 2004, the first literature review and the results on chronic venous insufficiency (CVI) endovascular treatments either by means of radiofrequencies (Closure®) as well as with endovenous Laser treatment (ELT). Middle term results for both techniques were considered effective and less invasive compared to stripping. Furthermore, he was correct when stating that Laser treatments were not all the same and therefore not very easily comparable.¹

Materials and methods

We have compared our results according to three different phases of our personal experience: the first one with a small randomized trial of Laser treatment *versus* stripping;² studies in progress on various aspects in a continuing series of 304 procedures (Table I); up to the experience known as Italian Endovenous-laser Working Group [IEWG].³

From the literature review it comes out that only few people declare to follow a precise protocol step by step, at the base of their personal experience.⁴ We performed an Internet search of the journal literature using the PubMed search motor. Once entered, the key word was only "Endovenous laser treatment" (in CVI). We identified 162 articles, reviews or abstracts

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published in the English language between 2001 and 2007, selecting 95. From this analysis the effectiveness of the treatment¹⁻¹⁰ out merges clearly, but from congressional contributes/debates in Italy, some critical aspects nonetheless emerge, over possible collateral effects or complications.

Firstly, there has been no common decision on the method name (ELT, EVL, EVA, EVTA besides commercial names) and on dedicated Groups or scientific Companies (IEWG, EAGLE, etc) with cultural implications as far as image towards patients, media and health organization is concerned.

Results

From the clinical point of view we assist to unfitting indications, while they should be the same as it is for stripping for about 50% of CVI surgery; never for simple reflux from Duplex exhibit. Regarding the instrumentation, will have to be considered devices at different wave lengths in diode employment (808, 810, 940, 980 nm) or Nd-Yag (1064, 1320 nm); as well as the insufficient attention to protocols instructions and several do-it-yourself. Recently it has been opportu-

TABLE I.—Patient demographics and Laser data.

Treated legs (2002-2005)	304
Female gender	70.7%
Male gender	29.3%
Age, mean	55 years
Great saphenous vein treated	93.6%
Small saphenous vein treated	4.3%
Anterior saphenous vein	2.1%
Collateral veins	1.8%
Stab phlebectomy simultaneously	87.3%
Procedure's time, mean	38 min
Percutaneous access	28.8%
Minisurgical access	71.2%
Anesthesia, epidural	25%
Peri-venous local	75%
Diode Laser (wave-length)	810 nm 5% 980 nm 95%
Power (average energy)	60 J/cm
Recanalization rate at 3 years	3.6%

nely recommended to use reporting standards.¹¹ Several non dedicated materials were found (Laser fiber without switch, ect); re-use of Laser fibers (regardless of rules on devices and lower efficacy of used fibers). The costs of the material appear "variable" for quality and market law.

Energies spent involve an uneasy standardization of the connection of the parameters for the variables thickness (mm) - power (W) - time (msec) - fluency (J/cm²); examples of higher dosage,¹² lower with longer exposure /T,¹³ review on behaviours for uncomparability.¹⁴ Association of proximal vein ligation to great saphenous vein (GSV) laser treatment is very rarely considered necessary. Since the incidence of reported deep venous thrombosis (DVT) and pulmonary embolism (PE) is quite rare among entire group of experiences, it would appear that GSV ligation, even in selected patients, may be a superfluous gesture.¹⁶

In spite of the initial doubts there is a good possibility to treat the small saphenous vein (SSV).¹⁷ The introduction in saphenous vein by percutaneous or minimally incision is the specialist's discretion. More debatable the choice of many entrance sites to the knee, to the ankle; directly from GSV-SSV junctions; up to contralateral femoral percutany.¹⁸ The opportunity to treat at the same time or deferring stab phlebectomy of collaterals is being discussed.¹⁹⁻²¹ In Italy for patient's preference we prefer contemporary treatment.

Results are not very easily comparable: the majority appears well balanced with distance obliteration percentage higher than 90% and significant satisfaction reported by patients, but range goes from enthu-

siastic²² to cautious when obtained from RCT.^{2, 23} Follow up has now reached 7 years; for many experiences however the necessary time beyond 3-5 years has not been reached.¹

Discussion

In the main, from procedure facts and from various literature experiences, it emerged that specific counter-indications connected to morphology or diameter of the vein to be treated are very few. Therefore the consequent simplicity of the vein catheter procedure and endovascular treatment conduction carried out by the operator show a low procedure difficulty and low perioperative accidents, which on the contrary, without an accurate critical vision of the procedure itself could subsequently invalidate the results at a distance, increase complications in the short term, and damage the image of the endovascular treatment, jeopardising certainty of a centenary surgery. The GSV is resulting to be the target of CVI treatment more often taken into consideration in the thigh portion, as a result of clinical necessities and hemodynamic evidence, but also due to the risk of damaging the saphenous nerve in its tract of the leg. This neurological risk explains why the SSV is being treated more occasionally with endoluminal procedure; while personal experience on approximately 20 cases and SSV case studies treated with diode Laser¹⁷ counter-vent this opinion. On the contrary it is recommended to inform on wrong hemodynamical indications (preservable saphenous vein always useful as possible graft), vein isolation not indicated with unesthetic incision, as well as the employment of non dedicated procedure material or their re-use out of device rules and the reductions of efficacy of second-hand fibers, which alter the results analysis as far as efficacy, safety and satisfaction are concerned.

Significant and exclusive index concerning the choice of the appropriate surgery method to be performed on patient, such as symptoms, signs, gravity index, patient and surgeon satisfaction, survey of quality of life and on the other side the instrumental plan with Duplex, could alterate the result on the long distance. On the other hand, determined the relatively satisfactory correlation between the evidence of a reflux at saphenic troncular level and the presence of varicous vein and/or venous symptom, sometimes it is demonstrated the absence of correlation between symptoms

and cosmetic result evaluated by the patient and the presence of reflux by the Duplex.

The excellent results on clinical basis and in correlation between the results monitored with Duplex and clinical examination, show however several elements which validate the procedure. Postsurgical course is less painful in the endovenous procedure, going back to normal activities is faster and convalescence is shorter. Analysing postsurgical complications, neurological disease seems frequent after endoluminal treatment, more denounced than described, gradually disappearing.

On the contrary, haematomas along the treated vein are less important in endoluminal procedures in absence of avulsion of collaterals, as it is in stripping. Bruises instead must be brought to the right dimension of scarce invasivity, rapid disappearance and anyhow secondary to local anaesthesia and not to Laser effect. Complications generated by tying of inguinal junction, such as infections and lymphatic complications, especially junction relapse, result to have low weight in absence of surgical GSV or SSV ligation. Rare but not to be underestimated residual skin hyperpigmentation.²⁴ Varicose endoluminal treatment has remarkable advantages compared to classic surgery in terms of improvement of postsurgery course and even more on evaluating results in the long term, unless of a conceptual and practical bad use of the procedure.

Conclusions

Today the risk encountered at the beginning of the experience is more evident, this resulting in a damage of image of the new treatment due to the conceptual and practical bad use of the procedure, with disappointing results and possible complications otherwise avoidable (DVT/SVT and others). We require a meeting of independent Consensus.

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