

Endovenous laser procedure in a clinic room: feasibility and side effects study of 1700 cases

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Abstract

Objectives: To assess the feasibility of saphenous veins ablation by laser in a clinic room. To study immediate and short term (1 to 6 months) complications and to pinpoint those that could be directly linked to this environment. Efficacy of the technique should also be documented.

Methods: Retrospective study (22 centres) carried out in France and Switzerland. Patients with insufficiency of great saphenous vein (GSV) or small saphenous vein (SSV). Clinical stages of clinical, aetiological, anatomical and pathophysiological classification (CEAP) were C2 to C6. Endovenous laser procedures were performed outside an operating theatre, under local anaesthesia and without high ligation. Efficacy criteria: occlusion of the vein and disappearance of the pathological reflux (duplex scan assessment). The side effects and complications were studied.

Results: A total of 1703 procedures (1422 patients) were performed; 74% of the patients were women. The mean age of the patients was 57. A total of 1394 GSV and 309 SSV were treated (mean diameters 7.2 mm and 6.4 mm, respectively).

Overall success level was 97% and mean length of veins treated was 40 cm for GSV and 21 cm for SSV. Energy applied in joules per centimeter was homogenous (mean and median 64 for GSV and 65 for SSV). Complications were rare and 'simple' apart from one pulmonary embolism which occurred 10 days after a GSV procedure, although no deep vein thrombus was found.

A total of two infections were observed: one was an infection localized at the site of access and the other was erysipelas.

Conclusion: Except 2 limited infections (0.1%), this large retrospective study of laser procedures performed outside the operating theatre did not reveal any significant specific complications as regards the environment required. The efficacy results were equivalent to those found in the literature. Regarding cost and constraints induced by operating theatre environment, the clinic room should be able to offer an easier and economic alternative option for saphenous veins ablation with laser.

Keywords: endovenous laser; varices; varicose veins; saphenous veins; outpatients; tumescent anaesthesia

Introduction

Over the last decade, endovenous techniques, whether thermal or chemical, for treating saphenous

veins have multiplied remarkably. Besides being effective, these methods offer several advantages: they are minimally invasive, can be performed as an outpatient procedure, and cause little (or no) interruption in the patient's physical or professional activities.

This expansion is also the result, on the one hand, of an improved understanding of venous pathology related to progress in ultrasound imaging and, on the other, a re-thinking of the set formula of systematic high ligation and indeed the conventional practice of surgery.^{1,2} High ligation in particular is

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prone to cause neovascularization, which, with post-operative morbidity, is one of the major disadvantages of conventional surgery, because it is the cause of most cases of recurrence.³⁻⁵

Endovenous techniques, which preserve the sapheno-femoral (SFJ) or the sapheno-popliteal junction (SPJ), will inherently reduce the possible risk of neovascularization. In May 2007, an analysis of the literature published in English and French pinpointed some 150 articles on radiofrequency (RF) and endovenous laser ablations.⁶

The literature published reveals that at one year or more, the level of efficacy recorded with this laser ablation is high (evaluation criterion = Duplex scanning), always above 90% and usually above 95%.⁶⁻¹⁰ Regarding the 'ideal environment', as highlighted by Gohel and Davies,¹¹ 'where to treat' is not straightened out so far: endovenous treatments may be performed under local anaesthesia (tumescence anaesthesia) in the setting of a clinic room. Nevertheless, in order to simultaneously and easily treat multiple veins avulsions, some clinicians prefer performing procedures under general anaesthesia in the operating theatre.

Few data are available that report on endovenous procedures carried out specifically outside an operating theatre. In 2002, Gérard¹² published a feasibility study of endovenous laser procedures carried out in a clinic room. This trial involved only a small number of patients (20 cases). Our retrospective study therefore aims to assess the characteristics of endovenous laser procedures carried out outside the operating theatre in a large population sample and numerous centres (22 investigators).

Objective

Primary endpoints

- To evaluate the feasibility of an endovenous laser procedure of saphenous veins performed in a clinic room;
- To study as a whole the complications and immediate- and short-term side effects (1 to 6 months), and in particular to highlight any that might be linked to this environment.

Secondary endpoints

- To study the efficacy of the method (by Duplex scanning): immediate and short-term outcomes (1-6 months);
- To identify specific practical requirements related to this environment and aim towards standardization.

Design of the study

Retrospective, multicentre study with 22 centres. All investigators were vascular physicians; 18 were French and four were Swiss. Most of them were experienced. Three of them were 'beginners' (experience of less than 50 procedures).

Patients and method

Recruitment objective: minimum 1000 endovenous laser procedures.

Patients:

- No specific requirements regarding age, sex or ethnicity;
- Suffering from insufficiency of the saphenous vein trunk (great or small saphenous vein) with or without reflux at the SFJ or SPJ.

Permitted clinical stages of clinical, aetiological, anatomical and pathophysiological classification (CEAP) C2 to C6.

The procedures absolutely had to be performed outside an operating theatre. This environment called for purely local, tumescence anaesthesia¹³ and no high ligation. Associated tributaries' treatment such as phlebectomy or sclerotherapy was permitted.

Data collection:

The following data were collected for each centre, and then centralized and analysed:

- General data on the patient (age, sex, body mass index [BMI]);
- Type of saphenous vein, trunk diameter;
- Procedure details:
 - Ultrasound-guided percutaneous puncture or introduction following denudation of the vein;
 - Ultrasound guidance of the entire procedure;
 - Laser technical characteristics (continuous or pulsed mode, power, total energy applied and energy applied in joules per cm);
 - Adjuvant therapy;
- Immediate outcomes (recording of side effects and complications; tolerability):
 - Duplex scanning;
 - Clinical examination;
 - Return to normal activity;
- Short-term follow-up (1 to 6 months):
 - Duplex scanning;
 - Clinical examination.

Criteria of evaluation

- Record of side-effects and complications – both immediate and short term (1 to 6 months), clinical examination and Duplex scanning;
- Evaluation of immediate- and short-term (1 to 6 months) efficacy. Criteria of success: occlusion of the vein and disappearance of pathological reflux (Duplex scan assessment).

In addition to this, the doctors were invited to complete a questionnaire on their procedures and environment (dedicated room, measures taken to ensure asepsis, equipment used disposable or autoclavable, etc.)

Results

General data (Table 1)

A total of 1703 procedures were recorded, involving 1422 patients. Recruitment, based on venous disease, involved more women (74%) than men. The mean age was 57 years (median 57), ranging from 15 to 92 years, and the mean BMI was 25. The mean CEAP was 2.8.

Characteristics of the veins treated and treatment performed (Table 2)

A total of 1394 great saphenous vein (GSV) and 309 small saphenous vein (SSV) were treated, i.e. 82% GSV. The mean diameters were 7.2 mm (median 7, ranging from 3 to 23) for GSV and 6.4 mm (median 6, ranging from 3 to 17) for SSV, respectively. The mean length of the vein treated was 40 cm for GSV and 21 cm for SSV. The mean

Table 2 Details of veins treated and treatment carried out

Type of vein (n)	GSV = 1394	SSV = 309
Diameter (mm)	Mean 7.2	Mean 6.4
Standing (large majority of cases)	Median 7	Median 6
Length treated (cm)	(Range 3–23) Mean 40 Median 40 (Range 13–85)	(Range 3–17) Mean 21 Median 20 (Range 5–60)
Energy applied (Joules/cm)	Mean 64 Median 64 (Range 25–153)	Mean 65 Median 64 (Range 38–100)

GSV, great saphenous vein; SSV, small saphenous vein

energy applied in joules per centimetre was 64 (median 64 J/cm) for GSV and 65 (median 64 J/cm) for SSV.

Side-effects and complications (Table 3)

Five deep vein thromboses occurred following the procedures, one of these three weeks after treatment, and only affecting a vein in the soleus muscle. The others were only parallel events at the junction level. Four were in the GSV group and one in the SSV group. Four superficial venous thromboses were observed, all in the GSV group.

A bilateral pulmonary embolism occurred 10 days after a bilateral GSV procedure in a 49-year-old woman with no personal or family history of thrombo-embolism or a special risk factor. No associated venous thrombosis, either superficial or deep, was found. No aetiological evidence could be found, and no history of thrombophilia.

Neurological impairment of sensation (dysaesthesia) was reported in 12 cases (9 GSV and 3 SSV), all of which had disappeared within three months. No motor disorders were recorded. Two confirmed infections were reported: one infection

Table 1 General data for the population recruited into the study

Inclusions	Number of procedures: 1703 Number of patients: 1422
Sex	Women 74% Men 26%
Age	Mean 57 Median 57 (Range 15–92)
BMI	Mean 25 Median 24 (Range 15–64)
CEAP	Mean 2.8 Median 2 (Range 2–6)

BMI, body mass index; CEAP, clinical, aetiological, anatomical and pathophysiological classification

Table 3 Side-effects and complications

TEE	STV = 4 (GSV group) DVT = 5 (GSV group: 4 and SSV group: 1) PE = 1 (GSV group)
Haematoma	5 (GSV group: 4 and SSV group: 1)
Neurological disorders	Sense-related 12 (GSV group: 9 and SSV group: 3) Motor-related 0
Infectious complications	1 (local) + 1 erysipelas (GSV group)
Burns	0
Other	0

TEE, thrombo-embolic events; STV, superficial venous thrombosis; DVT, deep vein thrombosis; PE, pulmonary embolism

occurred in the area around the site of access and one was a case of erysipelas (GSV in both cases). They required antibiotic treatment (good therapeutic response). The occurrence of these two infections had no explanation regarding the two physicians (they were both widely experienced), the environment (specific clinic room with good aseptic and safety conditions), the procedures (no incident), or the patients (healthy patients).

In one further case, where the patient presented a somewhat 'doubtful' inflammation around the site of access, the investigator decided to prescribe antibiotic cover without any clear, even clinical, proof of infection.

Five haematomas were spontaneously absorbed (4 in the GSV group and 1 in the SSV group). No burns or complications of any other kind were recorded.

Efficacy

Failures are presented in Table 4. Cases of failure to carry out the procedure (1%) include those procedures performed during the period of training. In the majority of cases, they were linked to problems of vein puncture (high-level venous spasm) or the impossibility of ascending the guide, on account of sinuosity or thrombotic sequelae.

In all but one procedure, the introduction step was by an echoguided percutaneous vein puncture (i.e. without denuding the vein). The global level of success for procedures performed, allowing for all failures, even partial failures, was 97%.

Auxiliary treatment

Patients received a mean six-day low-molecular-weight heparin for a median of five postprocedure days (range 3–11), both for the GSV and the SSV treatments. Most of them wore class 2 compression stockings (16–20 mm Hg) for periods ranging from one week to one month. Some operators applied a bandage in the first instance.

Table 4 Efficacy (level of failures)

Failure to carry out the procedure (failure to introduce or achieve catheterization, including during training)	N = 20 (GSV group: 19 and SSV group: 1) 1%
Short-term failures (1–6 months) (no or partial occlusion with reflux >0.5 second)	N = 35 (GSV group) 2%
Partial short term failures (permeable segment >5 cm without reflux)	N = 11 (GSV group) 0.6%

GSV, great saphenous vein; SSV, small saphenous vein

Report on procedures – environment

Most of the operators (82%) use a room dedicated to endovenous laser procedures. In all cases, the room was not their general consulting room. All have Duplex scan equipment and carry out all the procedures under echographic guidance (vein puncture, insertion of guide wire, catheterization, adjustment of the fibre position and tumescence for anaesthesia). All disinfect the skin prior to the procedure, and employ sterile fields and sterile disposable equipment for the procedures. Operators who perform phlebectomies have an autoclave.

All the French operators cover the sonographic probe with a sterile probe cover. The four Swiss operators do not use a probe cover, but disinfect the probes with a hydro-alcoholic solution (dipping), which they also use for their contact gel during all the procedures.

Discussion

In France, Switzerland and some other European countries, both vascular surgeons and vascular physicians perform endovenous procedures. Vascular physicians do it, customarily, outside an operating theatre, which is permitted in France by the health authorities, under strictly aseptic conditions.¹⁴ Vascular physicians do not perform conventional surgery but can perform phlebectomies.

This study involves a data collection of endovenous procedures (with or without phlebectomies or foam sclerotherapy) performed in a clinic room by vascular physicians. The aim was, above all, to assess side effects and complications that might be linked to this environment, in the conditions of physicians' usual practice.

Therefore, to strive for an objective and realistic analysis, no transmitted data have been excluded, in respect of all practices or indications (for example regarding saphenous vein calibres) or auxiliary treatments (compression for example). Vascular physicians have identical qualifications: experience in performing Duplex scanning and ultrasound-guided sclerotherapy.

The corollary of this homogeneity could be seen in the manner in which the procedures were performed as all the phases were carried out exclusively under ultrasound guidance:

- Percutaneous vein puncture;
- Insertion and positioning of the guide;
- Catheterization;
- Insertion and positioning of the fibre;

- Tumescence;
- End of procedure monitoring.

Of a total of 1703 procedures, only one vein denudation had to be performed for introduction of the catheter. All the other procedures were carried out via percutaneous vein puncture, for which the success rates are remarkably higher than those given in the literature. For instance, Agus⁹, reporting on a large series, provides a success rate for percutaneous vein puncture of 39.2% (422 cases) while 60.8% or 654 cases required denudation of the vein. The different results of our study may probably be explained by the training of vascular physicians, accustomed to ultrasound-guided sclerotherapy.

The most frequently used wavelength was 980 nm (Biolitec[®] device, Jena, Germany). One centre alone used an 810 nm wavelength. Whether the continuous or the pulsed mode, the mean energy applied in joules per centimetre was the same for the various centres regardless of whether the GSV or the SSV was treated (64–65 J/cm). To quantify our results we used the results recorded by Perrin in his meta-analysis as a yardstick⁶ (Table 5).

When compared with the literature, the side-effects and complications experienced with our procedures were rare and showed a poor specific link to the environment. Neurological disorders, such as dysaesthesia, one of the most commonly mentioned complications in the studies published, were considerably less common in our study (0.7%), even for the SSV (3 cases for 309 SSV, or 1%).

Using purely local anaesthesia, by tumescence, no sedation actually makes it easier to avoid causing a neurological injury during the procedure, since the alarm signal of potential pain is preserved. The application of this type of anaesthesia, approved for use in endovenous techniques,^{15,16} should be extended to all surgical treatments of varicose veins.

Perrin¹⁷ states: 'It is deplorable that general anaesthesia is still widely used in varicose vein surgery. Local tumescent anaesthesia can in fact be employed in the majority of cases, for conventional "open" surgery, endoluminal treatment or phlebectomy. General anaesthesia should only be considered for repetitive and potentially complex procedures'.

The level of infection was minimal (0.1%), but still remains unexplained even if in one case the absence of probe cover may be questioned. One pulmonary embolism was reported. The patient, a woman, was admitted to hospital with sudden-onset dyspnoea, 10 days after bilateral endovenous laser ablation of the GSV. After the treatment she had been given 3000 UI LMWH daily for a week. On admission the spiral scanner revealed a bilateral pulmonary embolism (lower lobe on both sides). Duplex scan examination was unable to detect any deep vein thrombus and both GSV were completely sealed. There was no thrombotic overflow into the femoral veins. No aetiological evidence could be found and no history of thrombophilia. There was no evidence to incriminate the laser treatment in this adverse event. Nevertheless, it is hard to believe that in a 49-year-old woman, with no particular antecedents and no known risk factors, the laser procedure did not play some part in triggering this event. However, the environment of a clinic room, coupled with the requirement of early resumption of walking, cannot be held responsible for this pulmonary embolism.

The efficacy rate of these procedures in the short term was high and close to that found in the literature (Table 5). As the aim of this study was not to demonstrate any superiority of efficacy in relation to the environment, we did not consider that it would be useful to assemble results with a follow-up of more than six months. The majority of investigators never prescribed time off work and the few who did, did so rarely and only for three or four days. Resumption of normal physical activity was described as 'rapid' but was not quantified. Investigators' practices as regards asepsis were homogenous and seem to meet globally the logical requirements for carrying out these procedures. Nevertheless, even if hydro-alcoholic solution dipping of the probe seems acceptable for some practitioners, we recommend probe cover.

Conclusion

Except two limited infections (0.1%), this large retrospective study of endovenous procedures, carried out in a clinic room and involving many centres, did not reveal any specific statistically

Table 5 Compared results (meta-analyses Perrin EMC 2007)

	EMC Perrin (2007) (Encyclopaedia of Medical Surgery)	EVLT study in clinic room
Efficacy	About 95%	97%
DVT	0–2.7%	0.3% (<i>n</i> = 5) EP 0.06% (<i>n</i> = 1)
SVT	1.7–10%	0.2% (<i>n</i> = 4)
Dysaesthesia	0–36.5%	0.7% (<i>n</i> = 12)
Haematoma	0.8–46%	0.3% (<i>n</i> = 5)
Infections	0	0.1% (<i>n</i> = 2)
Time off work (mean number of days)	4 (if procedure performed under local anaesthesia)	0 (sometimes 3 or 4 depending on centre)

significant complications in relation to the required environment. The side-effects were few and the outcomes as regards efficacy were equivalent to those found in the literature.

The requirements related to the environment generate a greater homogeneity of practice and a relative standardization of the procedure itself. In an increasingly difficult socio-economic context, any chance of reducing health-care costs while maintaining patient safety should be exploited. Regarding the cost and constraints induced by an operating theatre environment, a clinic room, with good aseptic conditions, should be able to offer an easier and economic alternative option for saphenous veins ablation with laser, above all if simultaneous multiple veins avulsions are not necessary.

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