Endovenous laser treatment of groin and popliteal varicose veins recurrence

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Abstract

Objectives: Recurrent varicose veins following surgery is a common, complex and costly problem in vascular surgery. Treatment for RVV is technically more difficult to perform and patient satisfaction is poorer than after primary interventions. Nevertheless, traditional vein surgery has largely been replaced by percutaneous office-based procedures, and the patients with recurrent varicose veins have not benefited from the same advantages. In this paper, we propose an endovascular laser treatment that allows reducing the invasiveness and complications in case of SFJ and SPJ reflux after ligation and stripping of the great and small saphenous vein.

Methods: 8 SFJ and 1 SPJ stumps were treated by endovascular laser treatment in out-patient clinic. Endovascular laser treatment was performed with a 1470 nm diode laser and a 400 μc radial slim™ fiber. Intraoperative ultrasound was used to guide the fiber position and the delivery of tumescent anesthesia. The gravity of chronic venous disease was determined according to the CEAP classification and the severity of symptoms was scored according to the revised Venous Clinical Severity Score (VCSS).

Results: The average linear endovenous energy density was 237 J/cm. Patients return to daily activities after a mean of 1.9 days after. The VCSS improved drastically from a mean of 8 pre-interventional to 1 at day 30 and until one year. During the follow-up period (mean 8 months, range: 5–17 months), all the stumps except one were occluded. All patients were very satisfied or satisfied with the method. No severe complications occurred.

Conclusions: Office-based endovascular laser treatment of groin and popliteal recurrent varicose veins with 1470 nm diode laser and radial-slim fiber is a safe and highly effective option, with a high success rate in the early post-operative period.

Keywords
Laser treatment, endovascular treatment, saphenous vein, recurrent varicose vein after surgery

Introduction

Recurrent varicose veins (RVVs) following surgery are a common, complex, and costly problem in vascular surgery. Treatment for RVV is technically more difficult to perform and patient satisfaction is poorer than after primary interventions.¹

Despite improvements in preoperative evaluation and methods of treatment, recurrence following varicose vein surgery is reported to occur in between 20% and 80% of cases, depending on the authors and the evaluation method, with increasing prevalence attending additional years of follow-up.²–⁷

Possible sources of reflux that caused recurrence are:

1. Neovascularization. The presence of reflux in previously ligated sapheno-femoral junction (SFJ) caused by development of thin incompetent serpentine veins linked with a thigh varicosity.⁸–¹¹

2. Tactical or technical error. The persistence of venous reflux in a saphenous trunk resulting from erroneous or inadequate preoperative evaluation and inappropriate surgery (tactical) or the persistence of venous reflux due to inadequate or incomplete surgical technique (technical).¹²–¹⁶

3. Disease progression. The development of reflux in sites where there was no evidence of neovascularization or tactical and technical errors.¹⁷–²⁰

RVV can also be classified into radiologic and clinical; importantly, radiologic recurrence does not necessarily
translate into clinical recurrence. However, most patients with RVV become symptomatic, with various clinical presentations. According Perrin et al., most had uncomplicated varicose veins and swelling (70.9%), but the remainder had skin changes (29.1%). These authors have found multiple sources of reflux feeding the recurrence, though incompetence at the SFJ was present in almost half of the patients. Neovascularization (20%) was as frequent as technical failure (19%) and tactical error (10%), and a combined presentation was found in 17%.

According to other authors, up to 70% of recurrences are caused by new incompetence at the level of the previously ligated SFJ and sapheno-popliteal junction (SPJ). Neovascularization and mostly the inadequate primary surgery with failure to ligate flush with the SFJ or SPJ are the major causes of RVVs. The earlier after surgery recurrence occurs, the more likely its cause is a technical error during primary surgery.

RRVs tend to be more frequent after small saphenous vein (SSV) surgery than after great saphenous vein (GSV) surgery. During reoperation, Creton found an intact SSV in 13.6% of patients and a too long stump with recurrence from branches of the SSV trunk in 42.4% of patients. An even higher percentage is reported by Tong who found an intact SPJ and SSV in 28% of patients.

Marques reported that 54.5% of the ligatures were incorrectly placed in cases operated for recurrent varices.

Unfortunately, in case of RVVs related to a technical error, the second open surgery becomes even more difficult because of the potential presence of a mass of fibrous scar tissue involving the previously sectioned end of the GSV or SSV.

This operation also becomes more difficult in the presence of a cavernoma (Figures 1 to 3), i.e. a mass ectatic multilobed veins formed in the point of the previous SFJ and SPJ ligation, and consisting of one or more tributary veins and the saphenous stump, surrounded by the scar tissue that makes difficult the exposure of anatomical structures. The cavernoma is easily breakable and therefore bleeding, during isolation. To avoid such surgical problems, most authors recommend to perform the procedure proposed by Li in 1975. Although this operation allows to reduce some technical problems, post-operative complications (i.e. wound infection, bleeding, lymphorrhagia) are frequent and it is, however, not free from technical errors and possible new recurrences.

Phlebology is completely changed in the last 10 years, and traditional surgery has been largely replaced by percutaneous office-based procedures that can be performed under local or tumescent anesthesia with similar early and midterm results but with less discomfort to the patient, improved early QOL, and earlier return to work. But the patients with RRVs have not benefited from the same advantages. Since 1975, any really valid alternative treatment to the Li’s procedure has not been proposed, despite the strong technological evolution.

In this paper, we present our preliminary experience and we propose an endovascular laser technique that allows reducing the invasiveness and complications in case of SFJ and SPJ reflux after ligation and stripping of the great and small saphenous vein.

Patients and methods

Patients

Between October 2015 and May 2016, all consecutive patients who underwent EVLT for RVVs in the private office of two surgeons (CA, FRS), experts in venous disease and endovascular venous treatment, were retrospectively entered into a database. All patients signed an informed consent allowing the anonymous use of their data for future studies. The gravity of chronic venous disease (CVD) was determined in each leg according to the clinical–etiology–anatomy–pathophysiology classification (CEAP). The severity of symptoms was scored according to the revised Venous Clinical Severity Score (VCSS).

Patients who had occlusive arterial disease and women who were pregnant were excluded.

The saphenous stump diameter was measured as well as the length of the treated stump. Surgery duration and complete length of stay in surgical ambulatory were recorded.

Patients’ characteristics are presented in Tables 1 and 2.

EVLT procedure

EVLT was performed with a 1470 nm diode laser (Ceralas E; Biolitec AG, Wien, Germany) and a commercial kit (ELVeS Radial slim™ Kit/Venflon™; Biolitec AG) containing all the equipment for the procedure (16-gauge needle for percutaneous introduction, 400 µc radial fiberoptic). EVLT was performed in an operating room with an ECG and pressure gauges monitoring.

All veins were accessed percutaneously with DUS guidance (Vivid e, GE Healthcare, USA). Using the 16-gauge introducer needle, the laser fiber tip has been positioned within the inguinal or popliteal stump, in close proximity to the femoral or popliteal vein. After this manoeuvre, the plastic cannula was removed completely; otherwise, it could be molten through the applied energy Figure 1(b).
In all cases, intraoperative DUS was used to guide the laser tip position and the delivery of tumescent anesthesia (cold 5°C saline solution 0.9% + 1 fl of lidocaine 2% + 1 fl of bicarbonate); this was infiltrated generously around the vein stump by using a 25-gauge needle, creating a good halo effect and good compression of the vein. In case of incomplete or dubious compression of the stump, perioperative manual compression was also made.

Intravenous sedation with midazolam 2.5 mg was made in all cases.

EVLT was carried out in a continuous mode with a power of 10 W. The pullback speed on the fiber was calculated to achieve a Linear Endovenous Energy Density (LEED: energy amount in joules divided by the treated vein length in centimeters) of at least 100 J/cm for the SPJ and 200 J/cm for the SFJ. If the obliteration of the stump and cavernoma could not be got

Figure 1. Clinical case. (A) Positioning the radial-slim fiber in saphenous stump and cavernoma. (1) A 69-year-old woman already subjected to high ligation and stripping of the GSV (scar highlighted by short white arrow) and subsequent re-do surgery according to Li (scar highlighted by long white arrow). A 2 cm saphenous stump (white curved arrow) of 10 mm in diameter feeding a groin cavernoma is still present. The radial-slim fiber (black arrow) is positioned between the two previous scars (white arrows); DUS is fundamental to guide the positioning of the optical fiber in the saphenous stump. (2) In this picture, the fiber tip is in the femoral vein (black curved arrow); therefore, the fiber has been retracted approximately 1 cm to position it correctly. Following the EVLT of saphenous stump also the cavernoma has been treated by LASER; in this case, the cavernoma, due to its significant tortuosity, has been treated in two stages, with two consecutive introductions of the optical fiber into it and with a further foam sclerotherapy treatment in support. (B) Results one year later. (1) The saphenous stump before (a) and one year after EVLT (b); there were no signs of reflux to the Valsalva’s maneuver. (2) The groin cavernoma has completely disappeared.
Figure 2. Clinical case: voluminous SFJ stump. (A) b-Mode. (1) Voluminous groin stump (21 mm) with significant reflux to Valsalva maneuver. EVLT results one week (2) and six months (3) after. A significant shrinkage of the residual SFJ stump close to the femoral vein may be noticed, in the absence of HEAT, already after one week, with the almost complete disappearance of the stump after six months. (B) Color-mode. Following the Valsalva’s maneuver, six months after (3) no signs of reflux, early recanalization, lymph node reactions or neovascularization were found.

Figure 3. Clinical case. (A) SPJ stump and superficial thrombosed cavernoma. Crossectomy and subsequent re-do surgery of the SPJ in a 76-year-old woman. In this case, the SPJ is positioned a few cm above the knee, as shown by the line drawn by the dermographic pen but for two times, the surgical incision was performed below it; a 3 cm saphenous stump of 10 mm in diameter is present yet, as well as a superficial cavernoma largely thrombosed, causing pain and embolic risk. In this case also, a residual short saphenous vein was treated at the same time; at six months, a sclerofoam of small residual retro-popliteal varicose veins was performed. (B) Results after EVLT of the saphenous stump after one week. (C) Results at one year.
with a single stick, two or more accesses were performed. After the procedure, venous outflow was checked immediately in the proximal deep veins by ultrasound. Persistent reflux in tributaries or below the treated vein was checked and additional treatment with foam sclerotherapy was applied if needed. The puncture site for foam sclerotherapy was at least 5 cm distant to the saphenous stump, directly into the cavernoma.

In case of residual refluxing, saphenous veins EVLT was also performed on them.

In the same session, all insufficient tributaries were treated by phlebectomy and/or sclerofoam.

Patients rated surgery global pain according to four types: “extremely,” “rather,” “slightly” and “not at all” painful.

Compression with 20–30 mmHg elastic stocking for two weeks was applied. In addition, as a precaution, low-molecular weight heparin for six days was given at prophylactic dosage to all patients. Patients were mobilized immediately after the intervention and were advised to walk regularly during recovery from treatment. A non-steroidal anti-inflammatory drug (diclofenac-sodium 75 mg) was prescribed for optional use.

**Follow-up**

Patients were scheduled for clinical and DUS assessments at 7, 90, 180, and 360 days after EVLT. VCSS, post-operative pain, patient satisfaction, side effects, adverse events, and recurrence rates were evaluated and recorded at each visit.

Post-operative pain was assessed on a 10-point scale ranging from no pain at all (0) to very painful (10).

Patient’s satisfaction was assessed by asking them the following questions: “Are you satisfied with the method being used?” (0 = very satisfied, 1 = satisfied, 2 = fairly satisfied, 3 = not satisfied); “Would you choose endovenous laser therapy again?” (0 = definitely, 1 = probably, 2 = don’t know, 3 = probably not, 4 = definitely not).

**Statistics**

According to the exploratory purposes of the study, only descriptive statistics was used.

Mean values and standard deviations were calculated using the statistics tool in Microsoft Excel 2007 version.

**Results**

The results are shown in Tables 1–4.

Nine patients with RVVs of the SFJ or SPJ were candidates for EVLT; in two of these patients, both among the first cases treated and one of them great obese (BMI: 42), for intra-operatively technical difficulties, it was not possible to carry out the EVLT; it was then opted for other methodical and these patients were excluded from the study. Seven patients were then treated.

In two cases, a bilateral laser procedure for bilateral groin recurrence was performed, in one case in the same session, in the other case in two different sessions.
No patient was lost during the follow-up period (mean 8 months, range: 5–17 months). Mean age was 66.4 years (min: 53, max: 83; SD: 10.4) and the mean body mass index (BMI) was 25 (min: 23, max: 27; SD: 1.7). Five patients (55.6%) were classified as C3, one patient (11.1%) as C2, 2 (22.2%) as C4, and one patient (11.1%) as C6 according to CEAP classification. All patients have had signs and symptoms; the most common was edema (six patients), heaviness (four patients), followed by pain (three patients) and itching (four patients).

The average diameter of treated stump, measured with patient in orthostatic position, was 10.2 mm (min: 7 mm; max: 21 mm; SD: 4.5).

The average length of treated vein was 1.6 cm (min: 1 cm, max: 3 cm; SD: 0.7) with a mean operative time of 45.6 min (min: 30; max: 90; SD: 18.1). The average LEED was 237 J/cm (min: 97 J/cm; max: 597 J/cm; SD: 164.8).

All patients were subjected to phlebectomies and in seven cases also to sclerofoam of the varicose tributaries during the same session.

Perioperative pain: four patients (57%) rated surgery global pain as “slightly” and three patients as “not at all” painful. Patients return to daily activities after a mean of 1.9 days (SD: 0.9).

In eight cases, no evidence of venous reflux or recanalization of the vein stumps treated with EVLT was found on DUS imaging at any time during follow-up. In one case, we have evidenced the initial recanalization of the stump after six months. Two cases of residual flow in tributaries veins were found at follow-up after six and nine months; in both cases patients were asymptomatic and a session of sclerofoam was performed.

Treatment effects on the VCSS-related signs or symptoms

The VCSS improved from a mean of 8 (min: 4; max: 11; SD: 2.5) pre-interventional to 1 (SD: 1.2) at day 30; it was still 1 at three and six months (SD: 1.2) and 1 at 12 months (SD: 1.4).

The EVLT substantially reduced symptoms of pain, venous edema, heaviness, and itching.

Complications and side effects

These data are synthesized in Table 3.

We did not observe any clinically apparent pulmonary emboli or motor or sensitive nerve lesions. No complications such as deep venous thrombosis or endothermal heat-induced thrombosis, skin burns, or the
formation of arterio-venous fistula occurred in any treated legs. Phlebitic reactions, which were defined by painful indurations with erythema at any location on the treated leg, were never observed in the treated limbs.

**Pain.** Four patients (57%) have had pain in the first post-operative week, with a mean intensity of 2.0 (SD: 2.0) in a scale of intensity from 0 to 10; all these patients have described it as mild and of short duration (2–5 days) and only two patients required analgesic therapy: mean 0.3 tablets (SD: 0.7) for all patients.

We did not find correlations between post-operative pain and the diameter of the treated veins or BMI.

**Patients’ satisfaction**

After one month and until 12 months, six (85%) patients were very satisfied with the method; the patient who presented the stump recanalization, despite the persistence of stasis eczema, thanks to the reduction of signs and symptoms, was satisfied with the treatment.

At day 30 and during the entire follow-up, the response to the question “Would you choose endovenous laser therapy again?” was “definitely” in 100% of cases.

**Discussion**

Surgical treatment for RVVs represents about 20% of surgical varices treatment, making it a common procedure for a vascular surgeon. Surgery for RVVs is generally more complex and aggressive than first-line treatment by means of stripping, particularly for redo surgery at the groin, whose complications can reach 40% of cases. The main cause of RVV at SFJ or SPJ is poor surgical technique or neo-vascularization. The postulated factors contributing to true varicose vein recurrence may broadly be divided into two groups: intraoperative factors (surgical technique, trauma, suture material) and postoperative factors (hypoxia, thrombosis, inflammation with pro-angiogenetic molecules). The postoperative factors, consequence of surgical trauma during crossectomy, are probably mainly responsible for determining the neovascularization recurrence. Performance of extensive crossectomy by most surgeons for almost 30 years has not reduced the frequency of procedures for varicose recurrence, but has led to the appearance of a new “source” of varicose recurrence, replacing the residual stump with neovascularization. RVV secondary to neovascularization is more common after open surgery than endovenous treatment or sclerotherapy. It contributed to 18% of the recurrences following open surgery compared with only 1–1.5% following endovenous treatment. Neovascularization is comfortable for the surgeon: crossectomy was done perfectly and RVVs are not related to a technical error; the cause of recurrence is unclear, poorly understood and largely due to unavoidable causes or related to factors intrinsic to the patient or to the inevitable evolution of the disease. In case of technical error, with the persistence of venous reflux at the SFJ or SPJ, RVVs were thought to be largely due to inadequate surgery especially when procedures were often performed by junior surgeons, leaving remnants of diseased GSV, SSV, or tributaries that enlarged with time. It is a pretext to blame postgraduates for such a frequent occurrence: a multi-center study identified this technical

<table>
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<th>Variables</th>
<th>One month (%)</th>
<th>Three months (%)</th>
<th>Six months (%)</th>
<th>Twelve months (%)</th>
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<td>Patients at follow-up (n)</td>
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<td>Patients lost to follow-up (n)</td>
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<td>Vein occlusion rate, n (%)</td>
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<td>9 (100)</td>
<td>5 (89)</td>
<td>2 (100)</td>
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<td>1.2 (1.3)</td>
<td>1.0 (1.4)</td>
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<tr>
<td>Very satisfied</td>
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<td>6 (85)</td>
<td>5 (100)</td>
<td>2 (100)</td>
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<tr>
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<td>1 (15)</td>
<td>1 (15)</td>
<td>0 (0)</td>
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<td>Fairly satisfied</td>
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<tr>
<td>Willing to choose EVLT again, n (%)</td>
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</tr>
<tr>
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<td>7 (100)</td>
<td>5 (100)</td>
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<tr>
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<tr>
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mistake in more than two-thirds of symptomatic recurrences. However, some investigations have reported no significant difference in the recurrence rates related to the surgeons' experience.

Therefore, the cause of groin and popliteal recurrence is alternately attributed to the patient or to graduate doctors. But the cause of these recurrences could be related to a third factor: crossectomy itself may not be the most suitable technique to avoid these kinds of recurrences. The manifestation of endovenous techniques that preserve the SFJ/SPJ has created doubts regarding the usefulness of crossectomy. Preservation of the SFJ during GSV reflux treatment enables preservation of some normal, competent tributaries (epigastric and perineal vein draining the residual stump).

Further, avoidance of high ligation of the SFJ or SPJ may be preferable because it is less invasive and is associated with a reduced risk of inflammatory reactions at the site of groin or popliteal dissection, resulting in a lower grade of neovascularization.

Other techniques have been developed to avoid the crossectomy, among which, external valvuloplasty was shown to be effective but adequate just for selected cases. An interesting strategic option has been recently proposed by Okazaki through a small skin incision and an echo-guided GSV ligation during endovenous ablation procedures. However, the ligation is performed 2 cm from the SFJ so not representing the same proper high ligation flush on the femoral. Mini-invasive high-tie by clip apposition has been recently proposed and it would seem to be a promising procedure. Some authors even recommend GSV surgery without high ligation of the SFJ.

Anyway, in our opinion, high ligation should be performed only one time; especially in case of groin or popliteal RVV, when a redo-surgery is performed, a more invasive treatment via groin or popliteal access may act as a new inflammatory trigger for neovascularization and subsequent high recurrence rates. According to the old axiom of Albert Einstein, “we cannot solve our problems with the same thinking we used when we created them.” Modern phlebology is characterized by a continuous advancement in devices that are designed to treat saphenous reflux; innovative technical options are constantly brought into market, leaving progressively behind the surgical option. EVLT is one of the most promising of these new techniques. It is an effective method to treat insufficient saphenous veins with occlusion rates to reach about 95%,

Thanks to the rapid evolution of the optical fiber, EVLT has also proven to be a versatile method to address a disease in itself multiform as the CVD. There is now the right fiber for any situation.

Bare fibers emit the laser beam in a straightforward manner out of the tip. This leads to a higher rate of penetrations of the venous wall. The newly developed fibers, like the radial ones, emit the laser energy radially around the tip directly into the venous wall; the light emission area is superior to the flat fiber, and the glowing tip of the fiber is not in direct contact with the vein’s wall and this permits a more homogeneous effect on the venous wall with less penetration which could lead to less pain and bruising. Some authors supposed also that damage induced by the use of the so-called wavelength-specific laser wavelengths (WSLWs), like the diode 1470 nm, with these newly developed fibers creates a lower inflammatory response to that produced from flat fibers and hemoglobin-specific lasers, but to date no histological confirmation is available. The recent introduction of the radial slim™ fiber represents a further evolution. It is designed to treat superficial venous reflux on perforator veins and small saphenous veins. The small diameter of the fiber allows it to cross the 16 G vein-flow; this fiber is then easy to handle, even in case of short stumps, and it is possible to cannulate the stump and if necessary introducing the optical fiber in the femoral vein, subsequently retracting the fiber and positioning it in the residual saphenous stump (Figure 2); the very restricted emission of laser beam in the radial manner, not in frontal one, allows to reduce the risk of DVT. The use of WSLW allows a further reduction in the risk of DVT or heat-induced thrombosis as the energy emitted at a wavelength of 1470 nm is much selective for the vein wall (which thanks to the tumescent anesthesia is collapsed on the optical fiber) rather than the hemoglobin in the blood. The direct transfer of energy and injury to the adjacent endothelium, rather than indirectly through the erythrocytes, most likely reduces the chance of upstream venous injury from propagated heat and reduces the chance of venous thrombosis from damaged endothelium. In addition, the more effective shrinkage of the vein, which occurs with WSLW, leads to less thrombus that can propagate proximally. This allowed us to deliver large amounts of energy (mean LEED: 237 J/cm) for short lengths of vein (1 cm in five cases) always achieving the complete obliteration of the stump and without observing any thrombotic complication. For their characteristic high pressure gradient and short ablation tract, we consider the saphenous stump the same way as an insufficient perforating vein (IPV); delivering large amounts of energy is mandatory. Previous studies in fact have shown that LEED values up to 400 J/cm in IPV ablation seem associated with improved results. Although a long-term follow-up is necessary, at short term it is evident the reduction and even the rapid disappearance (after four months) also of large cavernomas (greater than 2 cm, Figure 2), without noticing the presence of new vessels or lymph node reactions that
may suggest an inflammatory reaction or initial neovascularization process.

EVLT probably produces low inflammation on the treated vein and peri-venous tissue, even if large amounts of energy is delivered. Indeed, the post-operative pain is mild and resolves quickly (Table 3) and when specifically asked, actually it is related to the site of stab vein avulsion, rather than to the EVLA site. The recovery for the patient is quick and consequently satisfaction is very high (Tables 3 and 4). The percutaneous approach is helpful to prevent the proinflammatory stimulus of surgical groin access and the risk of the common complications of the classic re-do surgery at this level is averted. Even in the case of a mass of fibrous scar tissue involving the previously sectioned end of the GSV or SSV, the trauma during this procedure is minimal (a puncture with a 16-G needle), and there is not the extensive tissue dissection that occurs with the surgery and the consequent risk of wound infection, bleeding, and lymphocele.

This allows treatment to be offered to obese and to elderly patients with comorbidities that would preclude anesthesia for surgical treatment. Additionally, repeat treatment can easily be performed should recurrence arise again. However, owing to their specific anatomy, a percutaneous approach of saphenous stumps and cavernoma can be challenging and especially cannulation of short and tortuous veins is associated with a significant learning curve. Furthermore, the treating physician should be well aware of anatomical proximity of femoral and popliteal vein.

Conclusion

EVLT of groin and popliteal RVVs with 1470 nm diode laser and radial-slim fiber is effective and safe, and appears to be feasible, with insignificant post-procedural morbidity.

Although our series is small and follow-up is short, we believe this technique an excellent alternative to the intervention of Li for RVV due to long saphenous stumps.

Ethics approval

Our case report is exempt from the ethics review process as it does not involve research subjects but rather data available due to a permission form signed by the patients. This consent form allows for the publication of material relating to them in scientific and medical journals. The patients were competent and capable when signing this form.

Authors' contribution

CA took part in conception and design of the manuscript; CA and MD took part in the analysis and interpretation; CA and MD contributed to data collection; CA and MD were responsible for writing the article; CA, FRS, and MD took part in critical revision of the article; CA, FRS and MD took part in final approval of the article; CA and MD were responsible for statistical analysis; and CA takes the overall responsibility.

Declaration of Conflicting Interests

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