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ORIGINAL ARTICLES

Effect of the wide-spread use of endovenous laser ablation on the treatment of varicose veins in Japan: a large-scale, single institute study

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Background and aims: In Japan, stripping under general anesthesia, lumbar anesthesia and tumescent local anesthesia has been used in the treatment of primary varicose veins due to saphenous vein insufficiency. However endovenous laser ablation (EVLA) using a 980 nm diode laser has received National Health Insurance (NHI) coverage in 2011, while EVLA using a 1470 nm diode laser with a radial 2-ring fiber has received coverage in 2014. As a result, the use of EVLA has become widespread in Japan. We herein report on the results of varicose veins treatment at our hospital.

Subjects and methods: Two hundred eighty-nine patients with saphenous vein reflux who received treatment between October 2013 and December 2015 were included in the present study. The surgical results (operating time, complications, ablation rate, linear endovenous energy density [LEED], and the incidence of surgical site infections [SSI]) were retrospectively assessed and compared among the patients who underwent stripping (group A) and those who underwent EVLA (group B) according to the Japan Guidelines for EVLA.

Results: Group A and group B included 49 patients and 240 patients, respectively. Group B comprised 20 patients who underwent EVLA using a 980 nm laser (group B1) and 240 patients who underwent EVLA using a 1470 nm laser (group B2). The operative time in group A was 48 ± 16 minutes, whereas that in group B was 28 ± 10 minutes. The operative time, the length of the treated vein and LEED in groups B1 and B2 were 40 ± 11 and 27 ± 10 minutes, 36 ± 10 and 33 ± 10 cm and 84 ± 10 and 77 ± 18 J/cm^2, respectively. Furthermore, the mean operative time in group B1 (with no phlebectomy) was 31 ± 9 minutes, whereas that in group B2 (with no phlebectomy) was 22 ±7 minutes, which was statistically significant (p<0.05). The level of pain peak was day 1 in group A patients and on days 3-7 in group B1 patients; the group B2 patients felt little pain. Surgical site infection at the phlebectomy site was observed in two group B2 patients. EVLA resulted in an occlusion rate of 99.6% at approximately two years after surgery.

Conclusions: This study showed that EVLA using the 1470-nm laser caused less pain and bruising than EVLA using the 980-nm laser. The operative time of EVLA was approximately 9 minutes shorter than that of stripping. Therefore, EVLA using the 1470-nm laser might be the first treatment of choice for patients with saphenous vein reflux. However conventional surgery remains important because EVLA is not suitable in cases in which the diameter of the saphenous veins is >20 mm or in patients with highly tortuous veins.

Key words: varicose veins · endovenous laser ablation (EVLA) · surgical site infection (SSI) · radial 2ring fiber

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Introduction

Stripping under general anesthesia and lumbar anesthesia has been performed in the treatment of patients

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with primary varicose veins due to saphenous vein insufficiency. The first report on the performance of stripping under tumescent local anesthesia (TLA) [1] using low-concentration local anesthesia was published in 1999 by Proebstle et al. [2] Stripping under TLA has since been reported from Japan. [3] As a result, it has been possible to perform stripping operations as day surgery. In the United States, insurance coverage was provided for the use of 980 nm and 1470 nm diode lasers in 2002 and 2008, respectively and endovenous laser ablation (EVLA) has been reported to achieve good results. [4-9] Ablation has also been performed using radiofrequency equipment. [10-12] In Western countries, endovenous thermal ablation (laser or radiofrequency) is the golden standard for the treatment of saphenous varicose veins. [13] On the contrary, in Japan, EVLA using a 980 nm diode laser (Ceralas E Model 15 W/980 nm/200 µm, CeramOptec GmbH, Germany) and a bare-tip fiber (ELVeS Bare Fiber 600 µm, 70 cm, CeramOptec GmbH, Germany) (980 nm laser) received coverage in 2010. The use of EVLA began to increase in 2011. EVLA using a 1470 nm diode laser (LEONALD1470, CeramOptec GmbH, Germany) with a radial 2-ring fiber (ELVeS Radial 2ring™ fiber, CeramOptec GmbH, Germany) (1470 nm laser) and a VNUS® RF system using a Closure Fast™ catheter (San Jose, California, USA) was covered by National Health Insurance in 2014. As a result, the use of EVLA treatment has become widespread in Japan because the 1470 nm laser is associated with significantly less pain at the site of ablation than the 980 nm laser. [14]

The aim of the present study is to report the results of varicose veins treatments that were performed in our hospital in the current situation where EVLA has spread rapidly with the development and introduction into clinical practice of these laser devices.

Materials and method

Two hundred eighty-nine patients who received treatment for saphenous vein reflux at the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ) between October 2013 and December 2015 were included in this study. The veins were examined with the patient upright to determine venous reflux, which was defined as a retrograde flow of >0.5 seconds in duration with duplex ultrasound (US) imaging. The diameter of the GSV or SSV was measured at the level of the SFJ or SPJ, respectively. The CEAP classification of varicose veins was determined for all patients.

The "Guidelines for endovascular treatment for varicose veins - subcommittee report in 2009-2010" has been accepted as the medical guidelines for EVLA in Japan. [15] EVLA was therefore performed according to these guidelines.

EVLA was only performed using a 980 nm laser in patients who strongly wished to undergo EVLA (group B1) in the initial period when our hospital did not have a 1470 nm laser. Stripping was performed in the other cases (group A). EVLA using the 1470 nm laser was performed according to the guidelines from July 2014 (group B2). Stripping was performed in cases where EVLA was not indicated according to the guidelines (group A). As a general rule, the patients stayed overnight at the hospital. The surgical results (operative time, complications, ablation rate, and the incidence of surgical site infection [SSI]) were assessed retrospectively.

Procedures

The EVLA procedures were performed using a 980 nm laser and a 1470 nm laser. The methods of the procedure have been described previously. [16] Briefly, the site of the saphenous vein was first preoperatively marked under US observation. Antibiotics (CEZ) were administered to patients without antibiotic allergies just before surgery. All of the patients underwent EVLA under anesthesia with intravenous propofol, with oxygen supplementation. All GSVs and SSVs were percutaneously cannulated with an 18-gauge needle, either above or below the knee, under US control. If this could not be performed percutaneously, the saphenous vein was exposed to allow its puncture. A guide-wire was inserted through the needle and a 6 Fr introducer sheath was inserted. A radial 2-ring fiber was inserted through the sheath. The tip of the laser fiber was positioned at the distal site of the superficial epigastric vein or 2 cm below the SFJ under US control. The patient was then placed in the Trendelenburg position and 300-500 mL of tumescent local anesthetic (TLA) solution (450 ml of 0.9% saline, 40 mL of epinephrine-containing lidocaine and 15.5 mEq $NaHCO_3$) was injected into the saphenous compartment under US control. Thereafter, the saphenous vein was ablated from the distal site of the superficial abdominal wall vein or 2 cm below the SFJ to the puncture site, while the fiber was pulled back by hand. Eight watts (W) of laser energy was delivered using the bare fiber (group B1) and 10 W was delivered using the radial 2-ring fiber (group B2). An average of 80-100 J/cm² laser energy was applied via the bare fiber, while 100 J/cm² was applied via the radial 2-ring fiber. After EVLA, a phle-

bectomy was performed by the stab avulsion method when necessary. A compression bandage was applied over the course of the treated vein until the next morning. The patients then wore class II graduated compression stockings (approximately 27-40 hPa) for at least the next three months. The patients were advised to walk regularly during the recovery period. A nonsteroidal anti-inflammatory drug was administered twice daily for three days for pain control to patients in all of the groups. The patients were examined with US until the third day after surgery. Endovenous heat-induced thrombi (EHIT) were classified as class 1-4 according to Kabnick's classification. [17)]

For statistical analysis, the t-test was used to compare the results between the two groups. A p-value of 0.05 was regarded as significant.

Results

Two hundred and eighty-nine patients (male, n=99; female, n=190; average age, 65 ± 10 years; range, 34-88 years) underwent stripping or EVLA using the 980 nm laser or 1470 nm laser between October 2013 and December 2015. The preoperative CEAP clinical classes of the patients were as follows: C2, n=0; C3, n=195; C4, n=93; C5, n=0; and C6, n=1. The mean preoperative maximum diameter of the SFJ (in the supine position) was 7.6 ± 2.3 mm. Group A consisted of 49 patients, group B consisted of 240 patients. The mean operative times in the stripping (group A) and EVLA (groups B1 and B2) groups were 48 ± 16 minutes and 28 ± 10 minutes, respectively.

Twenty patients underwent EVLA using the 980 nm diode laser between October 2013 and June 2014; 220 patients were treated with the 1470 nm diode laser between July 2014 and December 2015 **(Table 1)**. The baseline characteristics of the two study groups (groups B1 and B2) are reported in **Table 2**. The mean operative time in group B1 was 40 ± 11 minutes, whereas that in group B2 was 27 ± 10 minutes, which was statistically significant (p<0.05). Furthermore, the mean operative time in group B1 (with no phlebectomy) was 31 ± 9 minutes, while that in group B2 (with no phlebectomy) was 22 ± 7 minutes, which was statis-

Table 1: Patient characteristics and intervention according to limb treatment by stripping or endovenous laser ablation.

	All	stripping	EVLA
Patients, No.	289	49	240
Age, y M±SD	65 ± 10	66 ± 12	65 ± 10
Male : female	99:190	21:28	79:162
Right : left	158:131	26:23	132:108
GSV : SSV	260:29	44:3	214:26
Diameter, mm M±SD	7.6 ± 2.3	8.8 ± 2.3	7.4 ± 2.2
Op time, min M±SD		48 ± 16	28 ± 10
With phlebectomy		53 ± 14	35 ± 9
With no phlebectomy		36 ± 16*	22 ± 7*
With phlebectomy, No.	148	35	113
DVT/PE		0 / 0	0 / 0
SSI	2	0	2*

EVLA, endovenous laser ablation; *GSV*, great saphenous vein; *SSV*, short saphenous vein; *M±SD*, mean ± standard; *Diameter*, Vein diameter; *Op time*, Operative time; *DVT/PE*, deep venous thrombosis / pulmonary embolism; *SSI*, surgical site infection (SSI of the puncture site was not observed but SSI of the phlebectomy was observed in two patients [0.77%]).

*: The mean operative time in group A (with no phlebectomy) was 36 ± 16 minutes, while that in group B (with no phlebectomy) was 22 ± 7 minutes, which was statistically significant (p<0.05).

tically significant (p<0.05). The length of the treated SV in group B1 was 36 ± 10 cm while that in group B2 was 33 ± 10 cm, which was not statistically significant. The ablation time was 382 ± 103 seconds (group B1) and 250 ± 93 (group B2), and the LEED was 84 ± 10 J/cm² (group B1) and 77 ± 18 J/cm² (group B2) **(Table 2)**.

Complications

This study showed that EVLA using the 1470 nm laser resulted in less pain and bruising in the postoperative period than EVLA using the 980 nm laser. The level of pain peaked on day 1 in patients who underwent stripping, and on day 3-7 in six patients (30%) who underwent EVLA using the 980 nm laser. In contrast, few patients who underwent EVLA using the 1470 nm laser reported that they experienced pain. As shown in **Table 2**, five patients (2.3%) in group B2 reported experiencing postoperative pain. Four patients (1.8 %) complained of pulling (induration along the saphenous vein). Bruising was observed in two patients (10 %) in group B1 and in seven patients (3.2%) in group B2. Paresthesia was observed in two patients (0.9 %) in group B2, and no patients in groups A and B1. The incidence of EHIT in group B1 was as follows: class 1,

Table 2: Patient characteristics, intervention and outcome according to limb treatment by endovenous laser ablation using the 980 nm and 1470 nm laser.

	980nm	**1470nm**
Patients, No. (%)	20 (8)	220 (92)
Age, y M±SD	65 ± 10	65 ± 10
Men : female	8:12	70:150
Right : left	8:12	124:96
GSV : SSV	17:3	197:23
Diameter, mm M±SD	8.5 ± 2.2	7.3 ± 2.2
Op time, min M±SD	40 ± 11	27 ± 10
With phlebectomy	42 ± 10	34 ± 8
With no phlebectomy	31 ± 9*	22 ±7*
Length, cm M±SD	36 ± 10	33 ± 10
LEED (J/cm) M±SD	84 ± 10	77 ± 18
Time, sec M±SD	382 ± 103	250 ± 93
Complications		
Pain, mild: moderate (%)	4 (20) : 2 (10)	5 (2.3) : 0
Induration along SV	-**	4 (1.8)
Bruising, mild: moderate: severe(%)	1 (5) : 0 : 1 (5)	6 (2.7) : 1 (0.45) : 0
EHIT class 1:2:3 (%)	4 (20) : 1(5) : 0	52 (24) : 4 (2) : 0
Skin burn (%)	0	1 (0.45%)
Nerve injury (%)	0	2 (0.90)

EVLA, endovenous laser ablation; *GSV*, great saphenous vein; *SSV*, short saphenous vein; *SV*, saphenous vein; *Diameter*, Vein diameter; *M±SD*, mean ± standard; Op time, Operative time; Length, Length of treated SV; *LEED*, linear endovenous energy density; *Time*, Ablation time; *EHIT*, endovenous heat-induced thrombus

*: The mean operative time in group B1 (with no phlebectomy) was 31 ± 9 minutes, while that in group B2 (with no phlebectomy) was 22 ±7 minutes, which was statistically significant (p<0.05).

**: no data

n=4 (20%); and class 2, n=1 (5%). The incidence of EHIT in group B2 was as follows: class 1, n=52 (24%); class 2, n=4 (2%). There were no cases of deep venous thrombosis, pulmonary embolism or serious complications in any of the groups. EVLA resulted in an occlusion rate of 99.6% at approximately two years after surgery **(Table 2)**. SSV reflux (from the SSV at a range of a few cm) and reflux to branch were observed in one group B2 patient at three months after the procedure. Stripping was performed to relieve the symptom.

There were no cases of SSI of the puncture site, however SSIs occurred at the site of phlebectomy in two patients (0.77%) in group B2. There were no other reported complications. No risk factors were associated with wound infection. The SSIs were treated conservatively with antibiotics and wound treatment. No SSI occurred in patients who underwent stripping treatment.

According to the Japanese guidelines, the stripping treatment was performed in 14 cases after July 2014, due to a preoperative diagnosis of deep vein thrombosis (DVT) in two patients and suspected DVT in one patient. The other cases included three patients with Lupus anticoagulant or anti-nuclear antibody and 3 patients in whom EVLA could not be performed due to anatomical reasons.

Discussion

Stripping has been performed under TLA in Japan since 2002. This has allowed stripping to be performed as day surgery due to its less invasive technique. [3] However, EVLA has undergone explosive growth since the 980 nm and 1470 nm lasers and RF EVLA received National Health Insurance coverage. In Japan, EVLA is performed by the members of six societies (the Japanese Society of Phlebology, the Japanese Society for Vascular Surgery, the Japanese College of Angiology, the Japanese Dermatological Association, the Japan Society of Plastic and Reconstructive Surgery and the Japanese Society of Interventional Radiology). The societies established a subcommittee for EVLA and approved and published the "Guidelines for endovascular treatment of varicose veins, 2009-2010." [15]

Our hospital has had a 1470 nm diode laser with a radial 2-ring fiber since July 2014. Since then, it has been used in the treatment of patients who satisfy the inclusion criteria for EVLA according to the Japanese guidelines. Stripping operations have been performed to treat 14 patients with varicose veins since July 2014. The reasons were as follows: saphenous vein of 20 mm in diameter (n=1), deep vein thrombosis (DVT) (n=2), suspected DVT (n=1), suspected anti-phospholipid antibody syndrome due to prolonged APTT (n=3) and Lupus anticoagulant or anti-nuclear antibody positivity (n=3). Ablation is possible when the saphenous vein is partially tortuous or partially obstructed, and in cases where the saphenous vein is punctured in two places. EVLA resulted in occlusion rates of 99.6% at approximately two years after surgery. The venous occlusion rate after EVLA with the 1470 nm laser and radial fiber has been reported elsewhere to be 99.6-100%. [18, 19] We were therefore quite satisfied with our results.

Patients in the 1470 nm laser group reported significantly less pain than those in the 980 nm laser group. The level of pain peaked on day 1 in patients who underwent stripping and then the patients who underwent stripping treatment did not complain of any pain, but the level of pain peaked on day 3-7 in patients who underwent EVLA using the 980 nm laser. The 1470 nm laser acts directly on the vessel wall through absorption by the interstitial water and the radial 2-ring fiber emits two distinct rings of the 1470 nm wavelength over 360°, [20-22] accounting for the name of this unique treatment. This high absorption characteristic in water at 1470 nm compared with absorption at 980 nm may reduce bruising and pain and saphenous veins can be evenly ablated. Moreover the operative time was reduced in the patients in group B2 because the laser energy was delivered at 8 W using the bare-tip fiber, but at 10 W using the radial 2-ring fiber which can emit the 1470 nm laser energy over 360°. It would therefore appear that EVLA using the 1470 nm laser will require no more energy than the 980 nm laser. The operative time in group B was shorter than that in group A, because we did not need to suture any skin wound. Moreover the sheath and laser fiber could be manipulated more easily and the procedure could be performed with a single operator, without an assistant. The EHIT class did not change in the group B1 and B2 patients, and no group B patients were classified as EHIT class 3. We will use anti-Xa inhibitors if necessary in patients with EHIT class 3. Because although they are expensive, anti-Xa inhibitors can be used on their own without heparin.

Conclusions

This study showed that EVLA using a 1470 nm laser caused less pain and bruising than EVLA using a 980 nm laser. EVLA using the 1470 nm diode laser with a radial 2-ring fiber is therefore one of the most accepted treatments for varicose veins in Japan. Other tech-

niques, such as venous puncture or injection into the saphenous compartment under US control are necessary and approximately twenty to thirty cases are required to gain the experience to perform these procedures efficiently. Gaining experience in the application of these techniques will lead to their operative times becoming shorter.

Moreover, it seems that EVLA can be performed more safely than stripping because it is performed under US control. We should, however, make a great effort to perform our conventional surgery techniques well, when required, because there are some cases in which EVLA cannot be applied, including cases where the saphenous vein is more than 20 mm in diameter or in highly tortuous vessels.

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