Safety and Effectiveness of Endovenous Laser Ablation Combined With Ligation for Severe Saphenous Varicose Veins in Japanese Patients

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Summary

Endovenous laser ablation (EVLA), which is a relatively new therapeutic option for saphenous varicose veins of the legs, is less invasive than conventional stripping surgery with ligation. In this study, we evaluated the safety and effectiveness of EVLA combined with ligation for severe saphenous varicose veins that were graded as ≥ C_4 by the CEAP classification. We treated 119 Japanese patients (141 limbs) between July 2005 and December 2007 utilizing a 1320-nm Nd:YAG laser. The obliteration rate of the treated veins was found to be 100% over the entire follow-up period (2.5 years). Consistent with this finding, all of the patients exhibited improved skin lesions (ie, skin pigmentation and ulceration). No major complications, including deep vein thrombosis (DVT) and nerve injury, were observed. A questionnaire survey with a reasonable response rate (66.4%) demonstrated that subjective symptoms and minor complications that were initially observed after EVLA, such as mild pain, numbness, indurations, and localized hot flashes, were remarkably improved by the end of the follow-up period. Furthermore, high levels of patient satisfaction were noted. Thus, EVLA combined with ligation constituted a safe and effective strategy for treating severe saphenous varicose veins in Japanese patients. (Int Heart J 2016; 57: 87-90)

Key words: 1320-nm Nd:YAG laser, Skin lesions, High patient satisfaction

Superficial venous insufficiency is a common medical condition that increases with age. Although stripping surgery with high ligation of the saphenofemoral junction (SFJ ligation) has been the standard treatment for great saphenous varicose veins with reflux, several effective alternatives are currently available.

Endovenous laser ablation (EVLA) is a minimally invasive technique that has become a common alternative in Japan. EVLA can be performed either with or without SFJ ligation, and controversy persists regarding whether performing SFJ ligation prior to EVLA is truly beneficial for decreasing the recurrence rate of varicose veins. Recent studies have demonstrated that EVLA with SFJ ligation results in less incompetent groin tributaries and less common recanalization after the procedure.[1)] Interestingly, however, the overall recurrence rate was not improved by performing SFJ ligation.[1)] This finding was inconsistent with a previous finding that the presence of incompetent groin tributaries contributed to the pathogenesis of recurrent varicosities.[2)] Neovascularization in the groin is one of the operative stress responses to the SFJ ligation procedure, and it acts as another principal cause of recurrence.[3-7)] Thus, the inconsistency noted above might be explained by the hypothesis that performing SFJ ligation not only leads to less incompetent groin tributaries but also augments neovascularization in the groin.

EVLA is a relatively new technique, and it tends to be applied for mild varicose veins that have been evaluated as class C_2 or C_3 according to the CEAP classification. Therefore, although EVLA has been performed in many medical institutions in Japan, the clinical outcomes of severe varicose veins (clinical classes of CEAP score ≥ 4) treated with EVLA have not been specifically reported.

In this study, we assessed the safety and effectiveness of EVLA combined with ligation for severe varicose veins (clinical classes of CEAP score ≥ 4) in Japanese patients.

Methods

Patients: Written informed consent was obtained from all of the patients involved in this study. Japanese patients with severe saphenous varicose veins (clinical classes of the CEAP score ≥ 4) were treated with EVLA combined with ligation between July 2005 and December 2007. Their ages ranged from

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30 to 80 years old (average: 59.3). The male/female ratio was 0.82.

EVLA protocol: Before the procedure, the patients were evaluated by clinical examination and duplex ultrasound scanning. EVLA was performed using a 1320-nm wavelength Nd:YAG laser at an output power of 5 W under ultrasound guidance. All of the patients received mild sedation and local anesthesia. Tumescent anesthesia (a combination of 450 mL of 0.9% sodium chloride, 50 mL of 1% lidocaine, and 16 mL of 0.7% sodium bicarbonate) was also administered to surround the whole target segments of varicose veins prior to ablation under ultrasound guidance. The great saphenous varicose veins were treated with EVLA following high ligation of the SFJ. A laser fiber was inserted into the central stump of the great saphenous vein (GSV) immediately distal to the ligated junction, and the fiber tip was advanced to the periphery. The GSV was ablated centripetally starting from below the knee. The small saphenous varicose veins were treated with EVLA following ligation of the saphenopopliteal junction. A laser fiber was inserted into the small saphenous vein (SSV) immediately distal to the ligated junction, and the fiber tip was advanced to the periphery. The central half of the SSV was then ablated. In both cases, the laser fiber was withdrawn from the periphery at 1 mm/s during ablation. After ablation, the legs were wrapped with elastic bandages for 24 hours, followed by elastic compression therapy (30 to 40 mmHg) for 4 weeks.

Follow-up: To assess the obliteration rate of the treated veins and major complications, physical examination and duplex ultrasound scanning were performed at 1 week, 1 month, 3 months, 6 months, 1 year, 1.5 years, and 2.5 years after the procedure. A questionnaire survey was also administered at 6 months, 1 year, 1.5 years, 2 years, and 2.5 years to study the following: 1) subjective symptoms, 2) minor complications; and 3) patient satisfaction.

Results

This study enrolled consecutive 119 Japanese patients (141 limbs) with severe saphenous varicose veins (clinical classes of CEAP score ≥ 4) that were treated with EVLA combined with ligation between July 2005 and December 2007. This study included 20 patients with recurrent venous insufficiency, who had been previously treated at other medical institutions. The underlying causes of recurrent varicose veins in these 20 patients are listed in Table I.

The varicose veins were evaluated according to the CEAP classification before the procedures: 121 varicose veins were graded as C_4, 15 as C_5 and 5 as C_6 (total 141). The number of incompetent perforator veins was counted, and the varicose vein diameter was measured by ultrasound examination (Table II). The obliteration rate was found to be 100% over the entire follow-up period (2.5 years) (Table III). Consistent with this finding, skin ulceration was greatly improved by the end of the follow-up period (Figure 1). Importantly, no major complications, including deep vein thrombosis (DVT) and nerve injury, were observed.

A questionnaire survey with a reasonable response rate (66.4%) demonstrated that subjective symptoms and minor complications, such as mild pain, numbness, indurations, muscle cramping, and localized hot flashes were improved remarkably by the end of the follow-up period (Figure 2). Furthermore, high levels of patient satisfaction were noted in the survey (Figure 3).

Discussion

EVLA is a minimally invasive technique that serves as an alternative to conventional stripping surgery. Because EVLA is frequently applied for mild varicose veins (class C_2 or C_3, according to the CEAP classification), the available clinical information regarding severe varicose veins (clinical classes of CEAP score ≥ 4) treated with EVLA has been limited. Therefore, the safety and effectiveness of EVLA for severe varicose veins were evaluated in this study. We observed excellent me-

Table I. Underlying Causes of Recurrent Varicose Veins

	Number of cases
Residual tributaries	10
Incompetent perforator veins	3
Neovascularization	4
De novo reflux in the saphenous vein	7

Average time from the first treatment: 10.2 years.

Table II. Varicose Vein Diameter and Percentage of Cases With Incompetent Perforators

CEAP classification	Varicose vein diameter (mm)	Incompetent perforator veins (% of cases)		
		Cockett	Boyd	Dodd
C_4	7.7 ± 1.8	5.7	1.4	1.4
C_5	10.6 ± 2.3	46.7	6.7	0.0
C_6	11.1 ± 2.3	20.0	20.0	0.0

* Varicose vein diameter (mean ± SD).

Table III. Obliteration Rate of Varicose Veins Treated With EVLA

	Procedures	# of limbs	Follow-up (years)	Obliteration rate (%)
Min RJ, *et al* 2003	EVLA without ligation	499	2	93
Sadick NS, *et al* 2003	EVLA without ligation	30	2	97
Timperman PE, *et al* 2005	EVLA without ligation	100	1	91
Puggioni A, *et al* 2005	EVLA without ligation	77	< 1	91
Kavuturu S, *et al* 2006	EVLA without ligation	66	0.75	97
Myers K, *et al* 2006	EVLA without ligation	396	3	80
Ravi R, *et al* 2006	EVLA without ligation	143	3	GSV:100, SSV:95
* Present study	EVLA with ligation	141	2.5	100

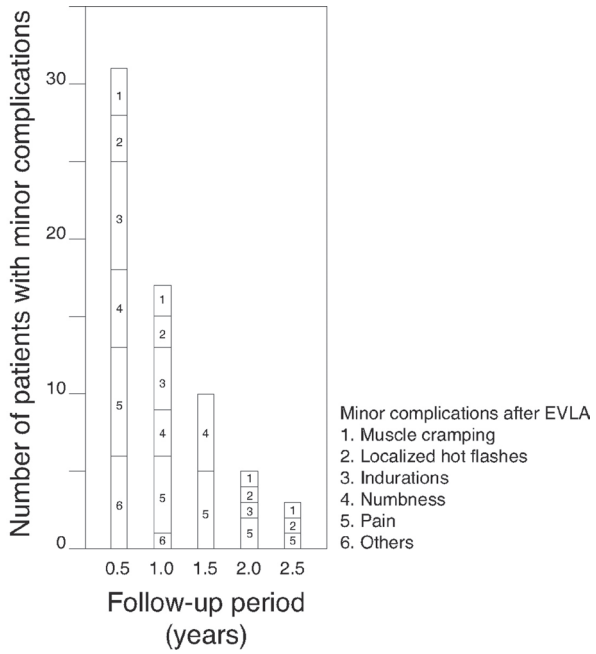

Figure 1. Minor complications after EVLA. Minor complications, such as muscle cramping, localized hot flashes, induration, numbness, and pain were initially observed after EVLA but had improved remarkably by the end of the follow-up period (2.5 years).

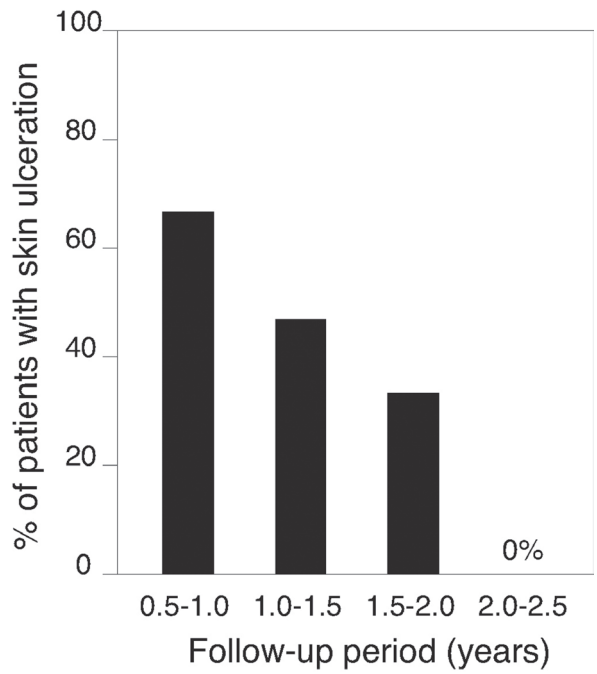

Figure 2. Skin ulceration. Skin ulceration was improved by the end of the follow-up period (2.5 years).

dium-term clinical outcomes (2.5-year follow-up period), indicating that EVLA is a safe and effective therapeutic option, even for severe varicose veins in Japanese patients.

High ligation of the SFJ is an essential and indispensable

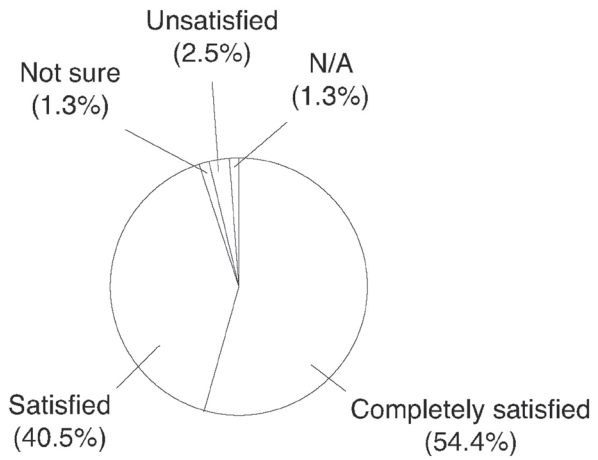

Figure 3. Patient satisfaction. High levels of patient satisfaction were revealed by a questionnaire survey.

part of conventional stripping surgery, especially when varicose veins measuring more than 10 mm in diameter must be treated. Because the presence of incompetent tributaries entering the SFJ increases the recurrence of varicose veins, it is also critical to perform complete resection of tributaries during SFJ ligation procedures prior to stripping.[2)] In contrast to stripping, it has been controversial whether performing SFJ ligation prior to EVLA decreases the recurrence rate of varicose veins.[1)] Because of this uncertainty, EVLA has generally been performed without SFJ ligation to render the whole procedure less invasive (ie, the incision required for cannulation of the peripheral saphenous vein is usually smaller than that required for surgical ligation in the groin). In addition to this cosmetic reason, EVLA without ligation is preferred because operative stress during the ligation procedure has been suggested to promote neovascularization, which enhances recurrence.[3-7)] However, we could not ignore the two potential risks associated with EVLA without SFJ ligation, ie, 1) early recanalization of the treated saphenous veins and 2) development of DVT after the procedure, particularly in this study, in which patients with severe varicose veins that measured approximately 10 mm in diameter were enrolled (Table II).[8-10)] To minimize these risks, we performed SFJ ligation prior to EVLA. Indeed, the obliteration rate was found to be 100% over the entire follow-up period (2.5 years) (Table III), which was clearly better than observed in the previous studies performed without ligation.[11-18)] Consistent with this finding, skin lesions and subjective symptoms were remarkably improved after treatment (Figure 1). Furthermore, no major complications, including DVT, were noted.

In this study, we were able to perform SFJ ligation through a 1.5- to 2.0-cm incision in the groin, which was considerably smaller than those reported in previous studies (ie, a 4- to 6-cm incision). We speculate that the small incision and the remarkable improvement in clinical symptoms resulted in the high levels of patient satisfaction that were noted in the questionnaire survey (Figure 3).

Conclusions: This study validated the safety and effectiveness of EVLA combined with ligation for severe saphenous varicose veins (clinical classes of CEAP score ≥ 4) in Japanese patients, showing excellent medium-term clinical outcomes. Be-

cause recurrent varicosities can emerge approximately 10 years after treatment, further long-term follow-up will be required.

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