Study on the Long-Term Results of Endovenous Laser Ablation for Treating Varicose Veins

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Abstract

Keywords

- ▶ endovenous laser ablation
- ▶ long-term results
- ▶ varicose vein
- ▶ saphenofemoral junction reflux
- ▶ recanalization
- ▶ recurrence

Background Endovenous laser ablation (EVLA) is widely performed since the early 2000s, but there are few long-term results.

Objectives The aim of this study was to evaluate the long-term results of EVLA employed for treating varicose veins of the lower limbs by duplex ultrasonographic study.

Methods A total of 24 limbs of 17 patients who underwent EVLA between 2004 and 2007 were examined with duplex ultrasonographic scans. The mean follow-up period was 66.1 months.

Results There were five recurrences of saphenofemoral junction reflux. The occlusion rate was 79.2% at a mean follow-up of 66.1 months. There were 14 recanalizations and 5 recurrences of the great saphenous vein. Five partial and nine total recanalizations were observed.

Conclusions EVLA is an effective and minimally invasive treatment for varicose veins. Our long-term result was acceptable, but the result was not outstanding.

Saphenofemoral junction (SFJ) reflux is the most common cause for the development of varicose veins of the lower limbs. The treatments for varicose veins have focused on closure of the SFJ and occlusion of the great saphenous vein (GSV), using many different methods.¹ One of these methods, endovenous laser ablation (EVLA) has been introduced recently for treating varicose veins and for reducing postoperative complications and provide earlier recovery than with standard surgery. There are many reports about its effectiveness and adverse effects.^{2–7} Today, EVLA is widely performed but there are few long-term results. Because of the benign traits of varicose veins, a long-term follow-up of patients has not been performed after EVLA. Previously, we reported the anatomical changes at the SFJ after EVLA, the relapse pattern and midterm results.⁸ We performed this study to elucidate the long-term results of EVLA and to extend and compare the results with our previous study.

Methods

Subject of the Study

The study subjects were 36 patients who received EVLA from November 2004 to October 2007. Of 36 patients, 19 patients refused interview and evaluation of their EVLA results, so a follow-up was possible in 24 limbs of 17 patients. Among the 17 patients, 13 (76%) were women and 4 (24%) patients were men. The mean age was 50.1 years. The mean follow-up period was 66.1 months (→ **Table 1**). Of these, duplex ultrasonographic scans were conducted on 16 limbs in 12 patients after 25.9 months in our previous study. This study was approved by institutional review board at the Eulji University Hospital.

Methods of Endovenous Laser Ablation

The operation was performed with the patient under local or spinal anesthesia. A 980 nm diode laser (Ceralas D15; biolitec

Table 1 Demographic data

Sex (M:F)	4:13
Mean age (y)	50.1 (35–63)
Mean follow-up period (mo)	66.1 (47–84)

AG, Jena, Germany) with a pulsed mode was used. We placed the laser fiber tip 2 cm below the SFJ. After tumescent infiltration, we activated laser firing and pulled the fiber backward at intervals of 3 to 5 mm, emitting for 1 second and stopping for 0.2 second. Pull-back speed was approximately 1 cm/3 sec. We start radiating heat by applying 12 to 14 W power at the beginning. We confirmed the adequacy of radiation dose by listening for liquid cavitation (boiling) and filling. If these were not noted, we increased the radiation dose. Each time we pulled back the laser fiber, we reduced the laser dose by 2 W power according to the level of the GSV. To avoid heat damage to the saphenous nerve, we ended the procedure at the upper third of the calf. In the post-EVLA period, we applied an elastic bandage and elastic stocking on postoperative day 1, and continued application of an elastic stocking about a month. We prescribed nonsteroidal anti-inflammatory drug for 1 week.

Examination Methods

The examinations were performed with the patient in a standing position with duplex ultrasonographic scans (LOGIQ 5; GE Medical Systems, Milwaukee, WI). Reflux was defined as positive when blood flow was present for more than 1 second after the patient performed a Valsalva maneuver or when squeezing the calf muscle. We checked for closure of the SFJ and the presence of reflux along the GSV to the level of the knee joint. We defined recurrence as when the reflux was still

present at the SFJ. Recanalization without reflux at the SFJ was not defined as recurrence.

Results

A total of 10 cases were of unilateral varicose veins and 7 cases were bilateral. Among the 24 limbs, there were five recurrences of reflux along the whole GSV. The occlusion rate was 79% at 66.1 months. The mean length of GSV treated was 42.05 cm (range, 30–53 cm), the mean total laser energy was 1,702 J and the mean energy density was 41 J/cm.

We classified the results of duplex scans into five groups according to recanalization and the reflux type in the GSV (►Fig. 1). Type I (five limbs) had total obliteration of the GSV from the SFJ to the distal GSV. Type II (five limbs) had obliteration of the GSV at the SFJ and partial recanalization without reflux at the distal GSV. Type III (seven limbs) was the most common with recanalization of the whole GSV without reflux. Type IV (two limbs) had recanalization of GSV with reflux at the distal GSV only. Type V (five limbs) showed reflux along the whole GSV from the SFJ.

Discussion

There have been tremendous changes to the treatment of varicose veins over the years. High ligation of the SFJ and stripping of the GSV have been considered as standard treatments for GSV insufficiency for more than one century and it is still adopted as the preferred method in the majority of the surgical centers. However, the increase in minimally invasive treatments such as EVLA, radiofrequency ablation (RFA), ultrasound-guided foam sclerotherapy and cryostripping have given excellent results.⁹ Most patients undergoing these minimal invasive treatments were satisfied with their

Fig. 1 Results of the Doppler examination. CFV, common femoral vein; GSV, great saphenous vein; SFJ, saphenofemoral junction.

results.^{10,11} The Society for Vascular Surgery and the American Venous Forum both recommend thermal ablation (EVLA or RFA) as safe and effective methods for treatment of incompetent saphenous veins. Among these treatments, EVLA represents one of the most common procedures and allows for the efficient management of large numbers of patients on an outpatient base.¹² Analysis of 64 prospective studies on cases of venous insufficiency reported occlusion rates of EVLA and conventional surgery as 94 and 78%, respectively, on duplex scan at 3 years.⁹ Recently, several randomized controlled trials (RCTs) comparing EVLA with conventional surgery have reported their results. Most RCTs reported that EVLA was as effective or more effective than surgery including technical success (clinical recurrence rate and duplex-detected saphenofemoral reflux), safety, postoperative pain, and quality of life.^{11–18} Carradice et al¹⁸ reported that EVLA had a significantly lower rate of clinical recurrence rate than surgery, 4.0 versus 20.4%, respectively. Also, there are a few large series of medium to long-term EVLA outcomes published. Agus et al⁵ reported a 97% occlusion rate in 1,076 procedures with a mean follow-up of 3 years. A subsequent series of 500 patients from France has reported a consistently well-maintained occlusion rate of 97% at 1 and 4 years.¹⁹ Ravi et al²⁰ reported a 7% recurrence rate in the longest follow-up with a mean of 6.7 years in 126 limbs treated by EVLA.

In our previous study in 2008, the occlusion rate of EVLA was 97% with mean follow-up period of 25.9 months.⁸ Our result was similar to other reports in the same period.^{13,14,16,21,22} However, in this study, recurrences occurred in 5 of 24 limbs without clinical symptoms and recanalizations were observed in 14 of 24 limbs during a mean follow-up period of 66.1 months. Our occlusion rate was 79% at 66.1 months, which is lower than other studies. There were also 14 recanalizations with or without reflux (→Fig. 1).

What is the mechanism of recanalization and reflux? EVLA acts by thrombotic occlusion. We postulate that the process and results of recanalization after EVLA might be similar to the natural history of acute deep venous thrombosis (DVT). In patients with an acute DVT, most recanalizations occurred within the first 6 weeks of acute thrombosis, with flow restoration in approximately 87% of completely occluded segments during this period.²³ In other reports, over half of the patients with an acute DVT showed complete spontaneous resolution of the thrombus within months.^{23,24} Thrombosis in the GSV after EVLA could be resolved spontaneously if the induced thrombosis did not become fibrotic. This hypothesis could explain our high recanalization rate. Several studies have reported that EVLA procedures are associated with a risk for recanalization and neoreflux through junctional tributaries.^{25,26} In our results, all patients with reflux at the SFJ also had reflux at the distal GSV. Such patients (types III and IV in →Fig. 1) might have a high possibility of reflux at the SFJ level later. However, there was no correlation between the follow-up period and patient types in our study.

What were the factors that contributed to recanalization or recurrence following EVLA in our study? First, the amount of energy administered during the procedure might be one of the factors. Proebstle et al²⁷ showed that the laser energy

delivery had an important effect on recurrence: low-energy delivery had worse results and more recurrences than higher energy doses. In a recent study, Pannier and Rabe demonstrated that a large vein diameter, when moderate energy delivery was used (48.6 J/cm) was associated with nonocclusion of the treated vein.²⁸ In addition, blood remaining inside the lumen might absorb laser light energy, consequently limiting light transmission to the vessel wall. Therefore, higher energy should be necessary to treat a larger GSV diameter and they recommended reducing the amount of blood in the vein by leg elevation.¹⁹ In another studies, successful occlusion of GSV has occurred when the energy density was more than 60 J/cm.^{29,30} In early period of EVLA, the procedure protocol was not established. Our procedure was performed in 2004 to 2007 according to the manufacturer's protocol. In our study, the level of energy delivery transmitted to GSV was 41 J/cm which was relatively lower than other studies and might be associated with higher recanalization rates of GSV. The long-term studies for higher energy density should be performed to find the proper treatment protocol.

Second, the distance from the SFJ to the fibrothrombotic obliteration point induced by thermal energy might play a role.¹³ This can have an important effect on venous tributaries and the rate of neo-revascularization later on, even though some evidence has been presented in the literature suggesting that EVLA, unlike surgery, is associated with a very low incidence of neo-revascularization.³¹ We radiated laser heat every 3 to 5 mm from 2 cm below the SFJ according to our protocol.

Third, residual blood absorbing laser light energy during EVLA might have led to thrombotic occlusion of the GSV. It is also possible that the veins had been occluded temporarily, but underwent early thrombus dissolution, which allowed preservation of the pretreatment vein diameter before intraluminal fibrosis.³² Therefore, thrombus dissolution is considered the most important factor in intraluminal neovascularization. Reduction of the thrombus burden might be helpful to decrease the need for recanalization.

Conclusion

The long-term results of EVLA in our study were acceptable in the treatment of primary varicose veins. However, recanalizations occurred persistently in our study. Revision of the EVLA protocol based on many RCTs and close follow-up might be necessary.

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