We performed a comparative study of surgical outcomes and venous functions between endovenous laser ablation with a 980-nm diode laser (EV group) and thigh stripping (ST group). There were no severe complications and initial success rates were 100% in both groups. In the EV group, preoperative symptoms improved in 94.3% of cases, the venous occlusion rate was 98%, and endovenous heat induced thrombosis had occurred in 11.9% (Class 3: 0.7%) at 12 months after the operation. Although comparative study of postoperative venous function by air plethysmography showed significant improvement in both groups, there was less recovery of postoperative venous function in the EV than in the ST group. (This article is a translation of J Jpn Coll Angiol 2015; 55: 13–20.)

Keywords: endovenous laser ablation, 980-nm diode laser, stripping, primary varicose vein of saphenous trunk, air plethysmography

Introduction

Saphenous type varicose veins have been generally treated by sclerotherapy combined with high ligation, stripping, or trunk sclerotherapy. High ligation of the great saphenous vein (GSV) is minimally invasive. However, concerning long-term results, the patency rate of the GSV trunk and the recurrence rate due to reflux are high, and previous studies comparing high ligation and stripping have shown a higher recurrence rate after the former. Based on these results, we changed the surgical procedure as the first choice from sclerotherapy combined with high ligation to thigh stripping combined with saphenous trunk sclerotherapy for the lower leg in July 2003, and obtained favorable treatment results using the latter combination. In January 2011, endovenous laser ablation (EVLA) with a 980-nm diode laser (ELVeS laser, Biolitec Inc., Jena, Germany) began to be covered by national health insurance system in Japan, providing a new choice. In October 2011, we also introduced EVLA, and have performed this procedure as the first choice for saphenous type varicose veins and obtained favorable short-term results.

We compared treatment results and pre- and postoperative venous functions between EVLA and stripping, and evaluated the possibility that EVLA is comparable to stripping or even can replace it with a review of the literature.
with 100 ml of 0.05% bupivacaine and 20 ml of 7.4% sodium bicarbonate. The procedures of both stripping and EVLA were previously reported.\textsuperscript{5–7} Trunk foam sclerotherapy for the lower leg was performed simultaneously with each surgical technique during the operation. As EVLA, GSV ablation was performed from 15 mm distal to the sapheno-femoral function (SFJ) or just distal to the superficial epigastric vein at a linear endovenous energy density (LEED) of 80.9 ± 3.7 J/cm. On the operation day, the entire lower leg was compressed using an elastic bandage. From the next day of the operation, the thigh was compressed using an elastic bandage for 3 days and the patients wore elastic stockings (medium pressure, stocking type) for 1 month. In the EV group, there was no patient who had an indication for EVLA but desired stripping. All operations in both groups were performed by three vascular surgeons including the author.

Complications during and after the operation and improvement of preoperative symptoms at 1 month postoperatively were evaluated in both groups. Statistically significant differences were analyzed using the $\chi^2$ test. In the EV group, ultrasonography was performed using the Aplio400 (Toshiba Medical Systems, Tokyo) on the next day as well as 7–10 days and 1, 6, and 12 months after the operation to evaluate GSV recanalization and the patency of branches near the SFJ and determine the presence or absence of reflux, deep venous thrombosis, and endovenous heat-induced thrombosis (EHIT).

To evaluate venous function, according to the method described by Christopoulos and Nicolaides,\textsuperscript{8} the venous filling index (VFI, ml/sec), venous volume (VV, ml), and residual volume fraction (RVF, %) were compared between the two groups using air plethysmography (APG: ACI Medical, San Marcos, USA). Based on the study by Nicolaides et al., the following normal ranges of the parameters were used: VFI, ≤2.0 ml/sec; VV, 80–150 ml; and RVF, ≤35%,\textsuperscript{8,9} However, since the VV is associated with the volume of the lower leg, individual differences are marked. Therefore, the differences between the pre- and postoperative VV values, not absolute values, were compared for the evaluation of improvement in venous stasis.

The mean VFI, VV, and RVF values obtained using the APG were expressed as the mean ± standard deviation. The ST and EV groups were compared using the Student's t-test, and the pre- and postoperative values in each group were compared using the paired t-test. P <0.05 was regarded as significant.

**Results**

**Comparison of treatment results**

As preoperative symptoms (complaints) in the EV group, lower leg dull pain was present in 73.4% (200/273 legs), swelling in 73.4% (200/273), leg cramp during night in 41.8% (114/273), itching/dermatitis in 36.8% (100/273), pigmentation in 19% (51/273), and thrombophlebitis in 6.8% (17/273). One month after the operation, the symptoms improved in 94.3% (257/273); the improvement rate for each symptom was 95% (186/200 legs) for lower leg dull pain, 88% (176/200) for swelling, 91.2% (104/114) for leg cramp during night, 91% (91/100) for itching, 70.6% (36/51) for pigmentation, and 100% (17/17) for thrombophlebitis. Each symptom significantly improved after the operation, and favorable postoperative results were obtained.

In the EV group, early GSV occlusion was achieved in all legs. In the ST group, the GSV could be removed and resected in all legs. Thus, the early success rate was 100% in each group. As intraoperative complications, pain during laser ablation was observed in 19.4% (55/273 legs) in the EV group and pain during GSV removal in 29.8% (55/184) in the ST group. In both groups, the operation could be completed by adding TLA anesthesia. There were no other intraoperative complications. As postoperative complications, within 7–10 days after the operation, thigh pain or discomfort was observed in 66.7% (182/273 legs) in the EV group and 51.1% (94/184) in the ST group and subcutaneous bleeding in 41.1% (112/273) in the EV group and 56.5% (104/184) in the ST group. There was no significant difference in the rate of each postoperative complication between the two groups. Neither deep venous thrombosis nor saphenous nerve damage occurred in either group.

Ultrasonography in the EV group showed GSV recanalization 12 months after the operation in two legs, and the cumulative GSV occlusion rate was 98%. In the two legs showing recanalization, GSV was complete patent from 5 cm distal to the SFJ, and although reflux was also observed, there were no symptoms. These legs have been followed up with compression therapy. EHIT occurred between the next day of the operation and 1 month after the operation in 11.9% (33/273); Class 3 (extension >50% of the femoral vein diameter) was observed in 0.7% (2/273), but there was no Class 4 (almost total femoral vein occlusion) case. We performed compression therapy for 1–6 months in the Class 1 or 2 cases and for 3 or 6 months in combination with oral warfarin administration in the Class 3 cases and all EHIT cases were recovered.

In the EV group, reflux at the terminal valve was present in 96.3% (263/273 legs) before the operation. However, 1 month after the operation, occlusion from 11.4 ± 6.1 mm distal to the SFJ was observed, and there was no leg showing residual reflux of terminal valve. Concerning the patency of branches near the SFJ, the superficial epigastric vein was patent 1 month after the operation in 83.5% (228/273), but no reflux was observed in any leg.
Other branches except the superficial epigastric vein were patent after 12 months in 12.6% (16/127), and significant reflux was present in 5.5% (7/127). All the branches showing significant reflux were veins ascending the medial or lateral side of the thigh and flowing into the area between the SFJ and GSV ablation site, but their names could not be determined.

Concerning trunk foam sclerotherapy for the lower leg, residual varicose veins were observed 1 month after the operation in 7.3% (20/273) in the EV group. On ultrasonograms, the GSV trunk in the lower leg was patent in 24.9% (68/273) after 1 month, but reflux was clearly observed only in 5.9% of them (4/68). No leg required additional treatment.

### Comparison of venous function (Figs. 1–3)

The VFI represents changes in the lower leg venous volume due to blood movement from the thigh to the lower leg and the degree of venous reflux. In both the ST and EV groups, the VFI values 1, 6, and 12 months after the operation were significantly lower than the preoperative value, suggesting that reflux interruption in the saphenous vein was effective. Comparison of the VFI between the two groups showed no significant difference in the preoperative values but significantly higher values 1, 6, and 12 months after the operation in the EV group than in the ST group (Fig. 1). This result was considered to be partly because branches remaining near the SFJ show reflux in the EV group unlike the ST group. However, ultrasonography 1 month after the operation showed reflux in only 2% of legs with patent branches near the SFJ. GSV recanalization was observed only in one leg (0.8%), and therefore, the cause of significantly higher VFI values in the EV group was unclear.

The VV reflects venous stasis of the lower leg. In both groups, the VV values 1, 6, and 12 months after the operation were significantly lower than the preoperative value, showing improvement in venous stasis. Comparison of the VV between the two groups revealed no significant difference in the value 12 months after the operation.
Positioning for EVLA

reported to be frequently observed early after the operation but improve within 1 month after the operation.

In our study, thigh pain or discomfort also occurred in 66.7% of the legs, which were treated by continuous thigh compression, and only a few required non-steroidal anti-inflammatory drugs due to disturbance in daily life but showed improvement 1 month after the operation. Bruising occurred in 41.1% of the legs, but improved in each leg 1 month after the operation. As other complications, transient sensory disturbance (paresthesia) was reported to be 0.8%–17.3%, thrombophlebitis in 0.3%–5.5%, hematoma formation in 0.8%–7.5%, and induration in 26.9%–33.8%.

Serious complications such as deep venous thrombosis pulmonary embolism, skin burns, and arteriovenous fistulas were reported extremely rarely, and were also absent in our study. EVLA not associated with serious complications may be a safe procedure.

The incidence of EHIT was reported to be 1.5%–15%, but Class 3 was observed only in 0.3%–1.6%, and no Class 4 case was reported. Spontaneous disappearance of EHIT with only follow-up of the course was reported in Class 1 and 2 cases and after anti-coagulation therapy in Class 3 cases. The two Class 3 legs we encountered showed spontaneous disappearance after compression therapy combined with warfarin administration for 3 or 6 months. To prevent EHIT, Mozes et al. reported that thrombosis at the SFJ can be prevented by flow from the superficial epigastric vein when ablation is started at 1 cm distal to the confluence of the GSV and

but significantly higher values 1 and 6 months after the operation in the EV group than in the ST group (Fig. 2).

The RVF reflects the indirect venous pressure of the lower leg. In both groups, the RVF values 1, 6, and 12 months after the operation were significantly lower than the preoperative values, showing improvement in venous hypertension. Comparison of the RVF between the two groups revealed no significant differences in the values 12 months after the operation but significantly higher values 1 and 6 months after the operation in the EV group than in the ST group (Fig. 3).

Discussion

Table 1 show reports in the literature on the results of EVLA with a 980-nm laser. The EVLA success rate (venous occlusion rate) after follow up for 6–48 months was reported to be 88.1%–100%, showing favorable early and midterm treatment results. The recurrence rate of varicose veins at the treatment site in studies showing this rate was 11.7%–28.4%. In our study, the venous occlusion rate after 12 months was 98%, showing favorable results as in previous studies.

Preoperative symptoms improved in 93.4% 1 month after ELVA, also showing the usefulness of this procedure. The reported complications after EVLA included pain at the site of EVLA, discomfort, bruising, sensory disturbance, thrombophlebitis, hematoma formation, and induration. Pain at the treatment site was observed in 9.3%–60.6% and bruising in 11%–65%. These were reported to be frequently observed early after the operation but improve within 1 month after the operation. In our study, thigh pain or discomfort also occurred in 66.7% of the legs, which were treated by continuous thigh compression, and only a few required non-steroidal anti-inflammatory drugs due to disturbance in daily life but showed improvement 1 month after the operation. Bruising occurred in 41.1% of the legs, but improved in each leg 1 month after the operation. As other complications, transient sensory disturbance (paresthesia) was reported to be 0.8%–17.3%, thrombophlebitis in 0.3%–5.5%, hematoma formation in 0.8%–7.5%, and induration in 26.9%–33.8%.

Serious complications such as deep venous thrombosis pulmonary embolism, skin burns, and arteriovenous fistulas were reported extremely rarely, and were also absent in our study. EVLA not associated with serious complications may be a safe procedure.

The incidence of EHIT was reported to be 1.5%–15%, but Class 3 was observed only in 0.3%–1.6%, and no Class 4 case was reported. Spontaneous disappearance of EHIT with only follow-up of the course was reported in Class 1 and 2 cases and after anti-coagulation therapy in Class 3 cases. The two Class 3 legs we encountered showed spontaneous disappearance after compression therapy combined with warfarin administration for 3 or 6 months. To prevent EHIT, Mozes et al. reported that thrombosis at the SFJ can be prevented by flow from the superficial epigastric vein when ablation is started at 1 cm distal to the confluence of the GSV and

Table 1: Literatures of EVLA with 980 nm diode laser

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>No. of legs</th>
<th>Follow-up (months)</th>
<th>Successful rate (%)</th>
<th>Pain (%)</th>
<th>Bruising (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmyttere</td>
<td>2007</td>
<td>511</td>
<td>48</td>
<td>97.1</td>
<td>9.3</td>
<td>60</td>
</tr>
<tr>
<td>Rasmussen</td>
<td>2007</td>
<td>69</td>
<td>6</td>
<td>96</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Pannier</td>
<td>2008</td>
<td>67</td>
<td>26</td>
<td>88.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doganci</td>
<td>2010</td>
<td>52</td>
<td>6</td>
<td>100</td>
<td></td>
<td>25</td>
</tr>
<tr>
<td>Hirakawa</td>
<td>2012</td>
<td>354</td>
<td>7</td>
<td>98.1</td>
<td>38.4</td>
<td>65</td>
</tr>
<tr>
<td>Scarpelli</td>
<td>2013</td>
<td>50</td>
<td>18</td>
<td>97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tabuchi</td>
<td>2013</td>
<td>127</td>
<td>6</td>
<td>99.2</td>
<td>60.6</td>
<td>47.2</td>
</tr>
<tr>
<td>Mozafar</td>
<td>2014</td>
<td>30</td>
<td>18</td>
<td>93.6</td>
<td>54.3</td>
<td>34.3</td>
</tr>
</tbody>
</table>

Table 2: English literatures of randomized clinical trial for EVLA with 980 nm diode laser versus stripping

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Follow-up (years)</th>
<th>No. of legs</th>
<th>Re-canalization rate (% EVLA/ST)</th>
<th>Recurrence rate (% EVLA/ST)</th>
<th>QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rasmussen</td>
<td>2010</td>
<td>2</td>
<td>137</td>
<td>4.3/2.9</td>
<td>26/37</td>
<td>N.S</td>
</tr>
<tr>
<td>Christenson</td>
<td>2010</td>
<td>2</td>
<td>204</td>
<td>6.7/0</td>
<td>9/10</td>
<td>N.S</td>
</tr>
<tr>
<td>Pronk</td>
<td>2010</td>
<td>1</td>
<td>130</td>
<td>8.5/0</td>
<td>9/10</td>
<td>N.S</td>
</tr>
<tr>
<td>Flessenkamper</td>
<td>2013</td>
<td>2</td>
<td>449</td>
<td>17.9/10.1</td>
<td>46.6/54.6</td>
<td>N.S</td>
</tr>
</tbody>
</table>

EVLA: endovenous laser ablation; ST: thigh stripping; QOL: quality of life
superficial epigastric vein. Hirokawa et al.\textsuperscript{10} recommend strong venous occlusion by adequate ablation of the vein at the time of the initiation of ablation. It is important to start laser fiber pulling after confirming adequate bubble generation at the time of the initiation of ablation. Based on these reports, we began to determine the location of the laser fiber tip from multiple directions using ultrasonography during operation, and start laser fiber pulling after confirming bubble generation for several seconds at the time of the initiation of ablation. The EHIT complication rate significantly decreased in the latest 50 legs (7.3%), compared with the rate (14.3%) in the legs treated earlier. We consider that EHIT is an unavoidable complication, but does not cause poor outcomes, and improves after follow-up observation or conservative treatment.

Table 2 shows randomized clinical trials (RCTs) of EVLA with a 980-nm diode laser (EV) versus stripping (ST) in the literature.\textsuperscript{18–22} The follow-up period was 1–5 years, and the recanalization rate of the treated saphenous vein was 4.3%–17.9% in the EV group and 0%–10.1% in the ST group, showing no significant difference between the two groups in each trial.\textsuperscript{18–20, 22} In our study, the recanalization rate 1 year after the operation was 2% in the EV group, being favorable similarly to the previously reported rates. In most legs showing recanalization in the EV group, the recanalization was not associated with clinical recurrence, and did not affect the venous clinical severity score (VCSS) or the quality of life (QOL),\textsuperscript{18,20,22} and the course has been followed up. The varicose vein recurrence rate was 9%–46.6% in the EV group and 10%–54.6% in the ST group, showing no significant difference between the two groups.\textsuperscript{18,21,22} The CEAP classification as a parameter of the clinical severity, VCSS, Aberdeen Varicose Vein Symptoms Severity Score (AVVSS), and the Short Form-36 score as a parameter of the QOL significantly improved after the operation in both the EV and ST groups, showing no significant difference between the two groups.\textsuperscript{18,20–22} In our study, the recanalization rate was similar between the EV and ST groups. Although the QOL was not evaluated in the recanalization cases, there was no aggravation of symptoms, varicose vein recurrence, or venous function, which suggested that follow-up observation is possible even in recanalization cases. In terms of this point, EVLA may be comparable to stripping.

A meta-analysis of EVLA and stripping showed no significant difference in the recanalization rate or varicose vein recurrence rate between the EV and ST groups but significantly lower rates of postoperative hematoma formation, wound infection, and pain in the EV group than in the ST group.\textsuperscript{23} Other studies showed no significant difference in QOL improvement, the VCSS, or AVVSS early after operation between the two groups and a significantly shorter period until return to normal activities, social activities, and work in the EV group than in the ST group,\textsuperscript{23,24} suggesting the superiority of EVLA. Although the QOL, VCSS, or AVVSS were not evaluated in our study, we consider these factors to be important, and intend to add them in the future evaluation.

We evaluated changes in venous function until 12 months after the operation. Our study was not a RCT due to differences in the treatment and observation periods between the two groups. However, to our knowledge, there have been no studies that compared venous function until 12 months after the operation between the two groups. In both groups, venous reflux, venous stasis, and venous hypertension significantly improved, showing favorable venous function even 12 months after the operation. However, the EV group showed significantly higher VV and RVF values until 6 months after the operation, a significantly higher VFI value even 12 months after the operation, and slighter improvement in venous function than the ST group. In the two legs with GSV recanalization in the EV group, the VFI, VV, and RVF values were not markedly high, and therefore, did not contribute to the significant differences between the two groups. In addition, although severe cases (C4b and C6) were included in the EV group unlike the ST group, they showed improvement in the postoperative venous function, and did not contribute to the significant differences between the two groups. In the ST group, the SFJ was exposed, and all branches were ligated and resected. In the EV group, branches remained near the SFJ, and these residual branches may have induced venous stasis due to reflux to the lower leg, resulting in the significant differences in venous function improvement. Ultrasonography 12 months after the operation showed reflux in 5.5% of limbs with patent branches near the SFJ, but the VFI value did not significantly differ between the presence and absence of patent branches. The cause of the significantly high VFI value in the EV group could not be clarified, further observation is necessary to determine whether patent branches, incompetent perforating veins, or deep venous reflux is associated with the clinical recurrence of varicose veins or recanalization.

**Conclusion**

EVLA with a 980-nm diode laser, which produced favorable surgical outcomes without severe complications and improvement in postoperative symptoms, is a safe minimally invasive procedure comparable to stripping. Evaluation of venous function using air plethysmography showed significant improvement after the operation in both groups but slighter improvement in the EV group than in the ST group. Further evaluation of long-term treatment results and venous function is necessary.
Disclosure Statement

The first author and co-authors have no conflicts of interest.

References