Comparison of Endovenous Laser Treatment for Varicose Veins with High Ligation Using Pulse Mode and without High Ligation Using Continuous Mode and Lower Energy

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Purpose: To compare two methods of endovenous laser treatment (EVLT) for primary varicose veins of lower extremities: first-EVLT combined with high ligation of great saphenous vein using pulse mode ablation and 12 W laser; second-EVLT without high ligation and using lower energy (10 W) and continuous mode.

Materials and Methods: Ninety-three limbs of 75 patients were treated by 980 nm diode laser into the great saphenous veins from June, 2003. In the first group of 45 patients, (HL group), we performed a division of the sapheno-femoral junction after high ligation and EVLT was done with a 12 W laser in a pulse mode. In the second group of 30 patients (NL group) EVLT was performed without high ligation with a 10 W laser in a continuous mode using a laser fiber drawing device.

Results: Operation time was significantly shorter in the NL group compared to the HL group (p < 0.05), and the early occlusion rates were 100% (HL group) and 97% (NL group). Subcutaneous bleeding occurred in 9 limbs (16%) in the HL group and 2 limbs (6%) in the NL group. In the NL group there was one case complicated with thrombus which extended into the femoral vein.

Conclusion: High ligation at sapheno-femoral junction is not necessary for EVLT and a lower energy continuous mode laser induces a lower rate of complications compared with a pulse mode ablation at a higher energy level. However, close follow-up with duplex scanning is necessary in early postoperative period.

Key words: varicose veins, endovascular treatment, laser, minimally invasive surgery

INTRODUCTION

Primary varicose vein is one of the most common disorders and is characterized by reflux of the tributaries of the great or short saphenous veins. Less invasive techniques such as ultrasound-guided foam sclerotherapy, radiofrequency ablation (RFA) and endovenous laser treatment (EVLT) were reported in the 1990s, and the follow-up results indicate these procedures might be as effective as surgical stripping. Above all, in Japan, EVLT was reported by Oda et al. in 2003 and has been clinically applied in a gradually increasing number of cases. However, it is disputed whether high ligation of the GSV is necessary, and whether pulse mode or continuous mode of laser ablation is preferable to obliterate saphenous reflux and to reduce complications such as deep vein thrombosis and subcutaneous bleeding. This report indicates the results of our use of the two methods of EVLT for primary varicose veins of lower extremities: first, with high ligation of the great saphenous veins using pulse mode ablation and second, without high ligation, using lower energy and a continuous mode ablation.
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Subjects and Materials

Treatment with EVLT for primary varicose veins was initially introduced at our institution in July, 2003, and to date we have treated 93 limbs of 75 patients by EVLT for reflux of the great saphenous vein (GSV). Of these patients, 32 were men and 43 were women, ranging in age from 30 to 77 (average 59) years. Eighteen patients suffered from bilateral lower limbs varicose veins. Patients whose CEAP classification was above 4 degree or who had common exclusion criteria were excluded for EVLT in this study. CEAP classifications were C2s: 46 patients and C3s: 29.

The occlusion and reflux of GSV were evaluated, and the diameter of GSV at 2 cm distal from sapheno-femoral junction (SFJ) was measured at standing position by duplex scanning using SSD5500 (Aloka, Tokyo, Japan). The application of the EVLT procedure to the patients was performed under the judgment and with the permission of the Institutional Review Board of Fukushima Medical University, and the patients provided written informed consent after detailed explanation of the treatment.

Data were expressed as mean ± standard deviation. Statistical differences were determined by t-test or by chi square test. Differences were considered significant at P < 0.05.

EVLT procedures

Patients were anesthetized by femoral nerve block and by a large quantity of adjusted local anesthesia of 0.1% lidocaine with epinephrine. The contents of the local anesthetic agent were isotonic sodium chloride 400 ml, 1% lidocaine containing epinephrine (1:100,000) 50 ml and 7% sodium bicarbonate 50 ml. If patients needed sedation, midazolam was added.

The first procedure of EVLT (HL group):

A diode laser UDL60 (wavelength 980 nm) and a bare tip type laser fiber (Olympus, Tokyo) were used. A skin incision, about 2 cm in length, was made at the groin and the sapheno-femoral junction and all the terminal tributaries were exposed. All the tributaries were dissected and high ligation of GSV was performed. Then a laser fiber was inserted in retrograde manner using a guide wire through a long 5 Fr introducer to the knee level, or we cut the GSV at knee level through a small skin incision and inserted a laser fiber into the GSV to the groin. At the Trendelenburg position, local anesthesia was injected and infiltrated to the surrounding tissue of the saphenous vein. Cauterization was done by drawing the laser fiber at a speed of 5 mm/second using 12 W output and 1.0 second pulse mode in which there was a 1.0 second laser delivery and 1.0 second rest. Preoperatively, the patients were examined and the position of GSV and of incompetent perforating veins were marked using duplex scanning. Perforating veins were diagnosed as incompetent if the vein diameter at the fascial level was more than 3 mm or if there was a reflux wave after calf manual muscle milking. Before EVLT, calf varicose veins were extirpated by stab avulsion and the incompetent perforating veins were ligated directly at the suprafascial layer. We
put a small gauze pillow on the cauterization site and compression dressing was maintained for one week using elastic bandages. In the period from June, 2003 to July, 2005, EVLT was done in this manner.

**Second procedure (NL group):**
To be less invasive, since August, 2005, we changed the techniques: the high ligation of GSV was omitted and the laser fiber was inserted into the GSV at the knee level via a small incision toward the SFJ. EVLT was performed using lower energy (10 W) and in a continuous mode. The laser fiber top position was carefully decided at just 2 cm distal from SFJ under ultrasound observation (Fig. 1). The laser was fired and the laser fiber was drawn by a drawing apparatus (Senko Ika, Tokyo) with speed of 5 mm/second. In the period since August 2005, EVLT was performed by the 2nd procedure only.

**RESULTS**

EVLT was performed in 93 GSV; 57 by first procedure (HL group) and 36 by second procedure (NL group). Operation time of 48 ± 18 minutes per one limb of NL group was significantly shorter than 59 ± 16 minutes of HL group (p < 0.05, Table 1). The diameter of GSV was not significantly different between 8.0 ± 1.9 mm of HL group and 8.2 ± 2.2 mm of NL group. The laser energy doses were 1429 ± 989 and 1328 ± 665 Joule respectively, but this made no significant difference. The early venous obstruction rate was evaluated by ultrasound one week after operation. In the HL group, there was obstruction in the whole cauterized vein in all 57 (100%). In the NL group 35 of the 36 GSV (97%) had obstruction. In the one case where there was no obstruction, the diameter of the GSV near the SFJ was 11 mm. Subcutaneous bleeding occurred in 9 limbs (16%) in the HL group and 2 limbs (6%) in the NL group. Pain which required analgesics were 7 limbs (12%) in the HL group and 4 limbs (13%) in the NL group. In one patient where thrombus extended to the common femoral vein, we performed surgical thrombectomy and added high ligation of the GSV (Fig. 2).

The longest follow-up period was 59 months. The average was 41 months in HL group and 21 months in NL group. Ultrasound observation was done and there was no case with recurrence of GSV reflux and no case with dilatation of the cauterized GSV more than 3 mm in diameter. Also, we had no case that needed re-treatment for the recurrence of varicosis.

**DISCUSSION**

EVLT to treat varicose veins with saphenous vein reflux was first reported in the 1990s and has also been actively applied and its usefulness has been reported in Japan.

<table>
<thead>
<tr>
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<th>HL-group</th>
<th>NL-group</th>
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<tbody>
<tr>
<td>Patients</td>
<td>45</td>
<td>30</td>
</tr>
<tr>
<td>Limbs (GSV)</td>
<td>57</td>
<td>36</td>
</tr>
<tr>
<td>CEAP classification</td>
<td></td>
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<tr>
<td>C2s</td>
<td>27</td>
<td>19</td>
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<tr>
<td>C3s</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td>Age, y (mean)</td>
<td>30–70 (58)</td>
<td>35–77 (59)</td>
</tr>
<tr>
<td>Gender Male, %</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>Operation time (min)</td>
<td>59 ± 16</td>
<td>48 ± 18</td>
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<tr>
<td>Diameter of GSV (mm)</td>
<td>8.0 ± 1.9</td>
<td>8.2 ± 2.2</td>
</tr>
<tr>
<td>Laser energy, joule</td>
<td>1429 ± 989</td>
<td>1328 ± 665</td>
</tr>
<tr>
<td>Follow-up, months (mean)</td>
<td>24–59 (41)</td>
<td>1–24 (18)</td>
</tr>
<tr>
<td>Early occlusion</td>
<td>56 (100%)</td>
<td>35 (97%)</td>
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<tr>
<td>Complication</td>
<td></td>
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<tr>
<td>Bruising</td>
<td>9 (16%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Pain</td>
<td>7 (12%)</td>
<td>4 (13%)</td>
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<tr>
<td>Thrombus extension</td>
<td>0</td>
<td>1 (3%)</td>
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<td>Retreatment</td>
<td>0</td>
<td>0</td>
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n.s.: not significant, GSV: great saphenous vein
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The first problem of EVLT is whether to do high ligation of GSV or not. The second problem is the power of laser energy to be used. And the third problem is whether to use a pulse mode or a continuous mode of the laser. In the HL group high ligation of the GSV was performed in each case. The laser energy was 12 W and a pulse mode was used. In the NL group, no high ligation was performed, the laser energy was 10 W and a continuous mode was used. First, the obliteration rate of the NL group without high ligation was equal to that of the HL group with high ligation with one exception noted above. The important advantage of omitting the high ligation is that it is less invasive because the groin incision is unnecessary. Further, because high ligation was not done, the operating time was significantly shortened, which made procedure less stressful for the patient.

The second problem was whether to use higher or lower energy laser. We feared that if a lower energy laser was used, the occlusion of the veins would not be sufficiently achieved. On the other hand, using a 12 W laser for the HL group, subcutaneous bleeding occurred in 9 limbs. This bleeding probably the results of perforation of the vein wall by the laser. For the NL group we reduced laser to 10 W. In this group, occlusion was achieved in all except one vein whose diameter near SFJ was 11 mm. And subcutaneous bleeding occurred in only 2 limbs. The lower energy laser is therefore to be preferred and will be used in the future. However, it was reported that higher amount of laser energy shows good immediate success rate and a significantly reduced recanalization rate of GSV. Therefore, the limit of laser power to obliterate the GSV should be decided according to the total amount of laser energy and to the occurrence rate of complications.

The final problem was whether to use a pulse mode or continuous mode. The pulse mode observed using an angioscopy (AF type 28C, Olympus, Tokyo), caused the febrile effect at intermittent vein wall portions whereas the continuous mode produced its effect continuously in one side of the vessel wall (Fig. 3). Although the pulse mode produced vein occlusion in 100% of the GSV, the continuous mode because it effects the entire vein, is more certain and is to be preferred and will be used in our department in the future.

In addition, 980 nm diode laser, EVLT of wavelengths of 810, 940 and 1320 nm were applied clinically, and at 1320 nm little pain and little ecchymosis was observed. To reduce ecchymosis and subcutaneous bleeding constant pullback of the laser fiber is important. For better results, the drawing instrument of laser fiber is very helpful.

If high ligation of GSV is not performed, there is a risk of DVT from the extension of the clot to the femoral vein. The occlusion of the GSV by EVLT is mainly caused by formation of thrombus. In our NL group, DVT occurred in one case. What can be done to avoid this when high ligation is not done? There was no definite relation between vein diameter and clot extension. The age of the patient is an important factor in the occurrence of DVT. Puggioni et al. reported an in inverse relation between the distance of GSV thrombus from the SFJ and the age of the patient. Most of the patients, they reported, who developed an extension of GSV thrombus to more than 2 mm from the SFJ were more than 50 years old. They suggested that DVT prophylaxis should be considered in patients over 50. Other studies also reported a significant increase of DVT in older patients.
Therefore, when high ligation is not done, prophylaxis of DVT is important especially in older patients and early postoperative duplex scanning should be performed to rule out proximal extension of the thrombus. In regard to DVT, a comparison of RFA and EVLT is enlightening. It has been reported that current rates of DVT for EVLT and RFA are similar (0.3–2.1%)\(^{17,18}\). Further, no pulmonary embolism has been reported with EVLT, but two cases have been reported after RFA\(^{19,20}\).

The following are considered reasons for excluding EVLT: ischemic limb, inability to ambulate, DVT, poor general condition, pregnancy, nursing, plans to become pregnant\(^2\) or difficult catheterization due to tortuous saphenous vein or saphenous vein rising to the skin\(^3,7\). It was reported that no CEAP classification and no vein diameter are considered reason to exclude EVLT. But we experienced a case of occlusion failure, and now exclude the patient with GSV more than 11 mm in diameter. Patients with blood coagulation disorders are at high risk of DVT and this is also a contraindication for EVLT, especially in elderly patients.

EVLT has been widely used for several years and a meta-analysis reported\(^{19,20}\) that EVLT is significantly more effective than RFA to obliterate insufficient veins, that EVLT has fewer side effects and with EVLT the health-related quality of life improved better and faster compared with surgical stripping\(^{20}\). However, the long term results and the possibility of the recurrence of varicose veins in patients treated by EVLT should be followed.

CONCLUSION

The results of our study lead to the following conclusion: First, EVLT can be carried out effectively without high ligation of the GSV, provided DVT prophylaxis is done especially for patients over 50 years of age. This is less invasive and the operating time is significantly shorter. Second, a 10 w laser is sufficient to effectively cauterize varicose veins and is recommended to avoid subcutaneous bleeding in 980 nm diode laser. Third, a continuous mode laser is preferable to a pulse mode in that the entire vein is cauterized rather than intermittent spots.

REFERENCES

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