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Intravenous Catheter-Guided Laser Ablation: A Novel Alternative for Branch Varicose Veins

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It is difficult to manage tributary varicose veins with endovenous laser ablation. Using the intravenous catheter-guided laser fiber to ablate the tributary varicose veins has been proposed. From April 2004 to December 2009, we randomly assigned 134 patients with 170 limbs for laser therapy, of which, 89 limbs in 74 patients were treated with laser ablation. The residual tortuous veins were abolished with the intravenous catheter-guided laser ablation (ICLA group), whereas residual varicose veins in 81 limbs in 60 patients were treated by stab avulsion (SA group). Patients were followed up with the median of 44.5 months after surgery. The outcomes and durability of treatment in both groups were evaluated. The primary end point was recurrence of varicose veins. In comparison with the SA group, patients in the ICLA group had fewer surgical incisions and morbidity, a shorter hospital stay, and returned to normal activity earlier. The overall 5-year recurrence of varicose veins was infrequent in the ICLA group but was much higher in the SA group (5.4% versus 20%, $P = 0.022$). ICLA provided better outcomes than conventional SA in managing the branched varicose veins and may be an alternative for the treatment of branch varicose veins.

Key words: Varicose veins – Laser ablation – Intravenous catheter

Varicose veins, visible dilated tortuous veins, are a sign of chronic venous disease. Traditionally varicose veins have been treated with surgical ligation and stripping. In recent decades, numerous alternatives have been introduced for the treatment of varicose veins. They include foam sclerotherapy, radio frequency ablation, as well as endovenous laser ablation (EVLA) with various wavelengths.[1,2] EVLA has numerous advantages versus the conventional approach.[3–5] However, its application has been limited in managing the residual varicosities. The branch varicose veins have been treated with microphlebectomy, liquid, or foam sclerotherapy.

Considering the advantages of laser therapy and the drawbacks with conventional therapy, in recent years, we have introduced an intravenous catheter-guided laser ablation (ICLA) to treat branch varicose veins. ICLA is a novel method to ablate tributary

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varicose veins with a laser fiber guided by an intravenous catheter. To evaluate the effect of ICLA, we have prospectively performed EVLA in conjunction with ICLA or stab avulsion, and have then evaluated the outcomes between EVLT in conjunction with the ICLA versus stab avulsion.

Patients

Ethical approval from the Hospital Ethical Committee was obtained to perform the randomized study on EVLT and ICLA for patients with varicose veins. From April 2004 to December 2009, a total of 170 limbs in 134 patients with varicose veins were prospectively randomized into two groups for laser therapy by opening an envelope approach. Eighty-nine limbs in 74 patients were treated with EVLT. The residual tortuous veins were abolished with ICLA (ICLA group), whereas residual varicose veins in 81 limbs of 60 patients were treated by stab avulsion (SA group). The manifestation of patients with varicose veins was categorized according to the clinical, etiologic, pathophysiologic classification.[6] Patients' data were prospectively entered in the computer to document clinical information, detailed operative procedure, and morbidity. All patients were detected and measured for reflux with duplex scanning with an Acuson Sequoia 512 (Siemens AG, Munich, Germany). Reflux was defined as a retrograde flow of more than 500 milliseconds in the superficial veins, deep femoral veins, and deep calf veins, or more than 1000 milliseconds in the femoropopoliteal segment after the cuff deflation.[7]

Patients who had a visible dilated varicose vein of great saphenous vein (GSV) and the blood reflux on the saphenofemoral junction were included. Patients with current deep vein thrombosis or significant arterial disease (ankle: brachial pressure index, <0.8), patients with a past history of surgical treatment for varicose veins, pregnant women, or patients younger than 18 years, and those patients ($n = 6$) who failed to provide written consent were excluded. All patients provided the written informed consent for the procedure and were informed of alternative treatment and the risks involved.

Methods

All patients received only intravenous anesthesia; no additional local anesthesia was used during surgical procedure. The surgical procedure basically followed the previous reports with some modifications.[8,9] The GSV was initially punctured at the ankle with an intravenous cannula, and a 5F (1.67 mm) endovenous catheter (Cordis, Miami Lakes, Florida) was passed over a guidewire (Cook Inc, Bloomington, Indiana). After withdrawal of the guidewire, a bare-tipped 600-μm diameter laser fiber was inserted and advanced through the sheath and positioned at GSV, 2 cm from the saphenofemoral junction, which was measured by the ultrasound scan. An 810-nm diode laser energy with 12 W power at a density of 60 J/cm was released in continuous mode while both the laser fiber and the sheath were withdrawn simultaneously at 2 mm/sec. Meanwhile mild extrinsic pressure with an icy saline pack was applied over the skin where the varicose vein was being treated to reduce the risk of skin burn.

ICLA was performed to ablate the tributary varicose vein through the intravenous catheter; the working conditions were the same as for EVLA. Specifically, the residual varicose veins were marked preoperatively and were punctured with an intravenous catheter attached to an 18-gauge needle. The needle was retracted after successful puncture, and the intravenous catheter was maintained *in situ.* The laser fiber was put into the intravenous catheter, then the intravenous catheter was pulled out approximately 1 cm while the laser fiber was held *in situ.* The tributary vein was ablated as in EVLA. This procedure was repeated 3–5 times to abolish all the tributary veins in each cluster of varicose veins. In the SA group, after treatment of GSV with laser ablation, the tributary varicose veins were managed with stab avulsion.

For both groups, at the end of the treatment, a layer of Vaseline gauze was applied over the course of varicose veins ablated with laser and followed by the cotton-roll crepe bandage. One week later they were replaced with medical elastic support stockings for at least 3 weeks. The prophylactic antibiotics (cefuroxime, 1.5 g) were given intravenously during surgery and a single dose of enoxaparin (4000 units) was injected subcutaneously after surgery. All patients were encouraged to mobilize as early as possible starting 1 hour after the procedure. They were provided with pain killers on discharge and were instructed to take only if required and to resume work and normal activities as soon as they desired and felt comfortable to do so. Postoperative pain was documented as 0–10 on the visual pain analogue scale.

At follow-up patients were reviewed by sonographers, who were blinded to the treatment procedure,

Table 1 Baseline characteristics of patients

	ICLA (%), n = 74	SA (%), n = 60	*P* value
Female	42 (56.75)	31 (51.67)	0.556
Mean age (yr)	39.58 ± 11.59	41.02 ± 12.06	0.484
Varicose veins in both legs	15 (20.27)	21 (35)	0.056
Family history	39 (52.70)	25 (41.67)	0.203
CEAP class			
C2	52 (70.27)	38 (63.33)	0.395
C3-C4	18 (24.32)	21 (35.0)	0.176
C5-C6	4 (5.40)	1 (1.67)	0.379
Location of lesion			0.717
Below the knee	56 (75.68)	47 (78.33)	—
Below and above the knee	18 (24.32)	13 (21.67)	—

All data are number and percentage; means ± SD.

CEAP, clinical, etiologic, pathophysiologic classification; ICLA, intravenous catheter-guided laser ablation; SA, stab avulsion.

Table 2 Surgical condition, length of hospital stay, and recurrence of varicose veins

	ICLA (%), n = 74	SA (%), n = 60	*P* value
No. of incision per leg	1.18 ± 0.64	5.17 ± 0.76	0.0001
Surgical time per leg (min)	53.74 ± 6.07	44.05 ± 8.04	0.0001
No. of patients requiring pain killer within 24 hr	11 (14.86)	25 (41.67)	0.010
Postoperative bleeding	28 (37.84)	35 (58.33)	0.018
Hospital stay (day)	1.2 ± 0.5	3.90 ± 1.01	0.0001
Medical cost (USD)	1333 ± 83	1250 ± 133	0.0001
Resuming normal activity within 72 hr	69 (93.24)	45 (75)	0.003
Long-term recurrence	4 (5.4)	12 (20)	0.022

All data are number and percentage; means ± SD.

ICLA, intravenous catheter-guided laser ablation; SA, stab avulsion.

with an Acuson Sequoia 512 (Siemens). In addition, the number and size of ecchymosis on the treated extremities were assessed by the surgical nurse who was blinded to the surgical procedure once the bandages were removed on follow-up. Mild bruising was defined as a bruise with a maximum diameter of 1 cm, whereas a severe bruise had a maximum diameter of 5 cm; the other bruises was classified as moderate. Thrombophlebitis was considered if there was a local hyperemia, edema of skin, tenderness, or indurated cord on the site of the laser ablated varicose veins. The postoperative bleeding was considered if the diameter of bandage soaked with blood was 1 cm or more on initial removal of the bandage on follow-up.

Anatomic pathophysiologic (clinical, etiologic, pathophysiologic) class was assessed and documented by the consulting specialist. Patients were followed up at 1 and 4 weeks after surgery and were evaluated with ultrasonography. All patients were instructed to walk and record the severity of pain, any analgesic drugs taken, swelling of ankle, bruise if any, and the time taken to resume normal daily activities or work, if applicable. The long-term follow-up was carried out at the surgical clinic, through outpatient's visits, phone calls and emails to evaluate the outcomes and the durability of treatment and recurrence of varicose veins.

Statistical analysis

Data analyses were performed using the statistical package SSPE software for Windows (version 13.0; Chicago, Illinois). A Student's *t* or Wilcoxon test was used for pain scores and the Fisher's exact test or χ^2 tests were used for comparing incidence of complications between follow-ups.

Results

A total of 134 patients were included, 74 underwent EVLA and ICLA, and the remaining 60 received EVLT and stab avulsion. Table 1 shows the baseline characteristics of the patients in terms of age, gender ratio, distribution of varicose veins, and clinical, etiologic, pathophysiologic class. There were no significant differences between the SA group and the ICLA group. Most patients were followed up for at least 6 months. In the ICLA group, 69 patients were followed up at the outpatient clinic (n = 29), by telephone (n = 28), and emails (n = 12); 5 patients were lost after the 6-month follow-up. In the SA group, 56 patients were followed up at the clinic (n = 34), by telephone (n = 16), and emails (n = 6), 4 patients were lost at 12 months after surgery. The median follow-up was 44.5 months, and the longest follow-up was 5 years.

In comparison with the SA group, the number of incisions (1.18 ± 0.64 versus 5.17 ± 0.75; $P = 0.0001$) and the incidence of postoperative bleeding in each leg (37.84% versus 58.33%; $P = 0.018$) in the ICLA group was less. The hospital stay (1.2 ± 0.5 day versus 3.90 ± 1.01 days; $P = 0.0001$) was shorter, although the surgical time spent on each leg (53.74 ± 6.07 minutes versus 44.05 ± 8.04 minutes; $P = 0.0001$)

Table 3 Postoperative complications

Variables	1 wk after surgery			4 wk after surgery		
	ICLA (n = 74)	SA (n = 60)	*P* value	ICLA (n = 74)	SA (n = 60)	*P* value
Pain	11 (14.86)	23 (38.33)	0.002	0	0	—
Skin burn	9 (12.16)	8 (13.33)	1.0	0	0	—
Ecchymosis	16 (21.62)	15 (25)	0.645	14 (18.91)	11 (18.33)	0.931
Phlebitis	7 (9.46)	9 (15)	0.325	2 (2.70)	6 (10.0)	0.16
Ankle edema	15 (20.27)	20 (33.33)	0.127	0	0	—
Paresthesia	4 (5.41)	6 (10.0)	0.314	0	3 (5.0)	0.087
Hematoma	0 (0)	3 (5.0)	0.087	0	0	—
Itchiness	20 (27.03)	29 (48.33)	0.011	0	0	—
Wound infection	1 (1.35)	4 (6.67)	0.248	0	0	—

All data are number and percentage.

ICLA, intravenous catheter-guided laser ablation; SA, stab avulsion.

was longer and the medical cost was higher (1333 ± 83 USD versus 1250 ± 133 USD; $P = 0.0001$; Table 2).

The complication rates were significantly higher in the first week than 4 weeks after surgery in terms of pain, ecchymosis, ankle edema, and itchiness (Table 3). Within 1 week after surgery, itchiness was the most common complication (27.03%), followed by ecchymosis (21.62%), ankle edema (20.27%), and pain (14.86%). The rates of itchiness (48.33% versus 27.03%; $P = 0.011$) and pain (38.33% versus 14.86%; $P = 0.002$) were significantly higher in the SA group than in the ICLA group (Table 3). No clinical evidence of pulmonary embolism was observed such as breathing difficulties or alteration in D-dimer level. Deep venous thrombosis was not discovered on the ultrasound scan. All patients reported to have tolerable pain and most did not use pain killers. In the ICLA group less patients than in the SA group required analgesic tablets within 24 hours after surgery (14.86% versus 41.67; $P = 0.01$). The pain score was higher in the SA group than in the ICLA group on days 1 and 3 after surgery (day 1: 7.91 ± 0.65 versus 6.85 ± 0.70, $P<0.001$; day 3: 5.98 ± 0.72 versus 3.02 ± 1.11, $P < 0.001$), but the pain was relieved and there was no difference between the two groups on day 5 (1.64 ± 0.68 in the SA group versus 1.71 ± 0.56 in the ICLA group; $P = 0.486$). The incidence of ecchymosis was similar in both groups (Table 3), but there were more severe type of ecchymosis in the SA group (0 versus 11.67%; $P = 0.003$; Table 4).

The amount of time until return to work or normal daily activities, and the number of analgesics taken were documented at the 4-week follow-up visit after surgery. Most patients resumed normal activities or light work, such as clerical work, within 72 hours after surgery. The percentage of patients who resumed normal activities within 72 hours after the procedure was higher in the ICLA group than in the SA group (93.24% versus 75%; $P = 0.003$; Table 2).

Discussion

Our finding demonstrates that ICLA provided better outcomes than conventional SA in managing branched varicose veins. In comparison with the SA group, patients in the ICLA group had fewer surgical incisions (1.18 ± 0.64 versus 5.17 ± 0.76; $P = 0.0001$) and morbidity, less hospital stay (1.2 ± 0.5 day versus 3.90 ± 1.01 days; $P = 0.0001$), and more patients resumed normal activity within 3 days after surgery (93.24% versus 75%; $P = 0.03$). To our knowledge, few articles are available using ICLA to ablate the tributary varicose veins.

Treatment of varicose veins with EVLT has been performed under tumescent anesthesia, which involves the injection of a certain volume of a very diluted local anesthetic solution subcutaneously to reduce pain, and the trunk of great saphenous veins are treated initially, and the option of treatment for branched varicose veins are determined at 3 months after the initial surgery. Usually we found that the most branched varicose veins are always present if

Table 4 Severity of ecchymosis assessed at 1 week after procedure

	ICLA (n = 74)	SA (n = 60)	*P* value
Mild	10 (13.51)	2 (3.33)	0.065
Moderate	6 (8.11)	6 (10.0)	0.938
Severe	0 (0)	7 (11.67)	0.003

All data are number and percentage.

ICLA, intravenous catheter-guided laser ablation; SA, stab avulsion.

left untreated. During the initial management of varicose veins, no matter what kind of procedures being used, the branched varicose veins are connected with deep veins through perforator. Therefore, the branched varicose veins should be treated simultaneously with the main trunk of the great saphenous veins.

The amount of time until return to work after conventional surgery is 8–21 days.[10,11] In our series, patients could return to work or perform daily activities on the day after the ICLA procedure. The medical cost in the ICLA group was higher than in the SA group (1333 ± 83 USD versus 1250 ± 133 USD; $P = 0.0001$). A visual analogue scale of 0–10 in the ICLA group was highest on day 1 and reduced dramatically in the days after surgery. The drawback of ICLA was that it took longer time to perform than SA, and the surgical time in the ICLA group was longer than in the SA group (53.74 ± 6.07 minutes versus 44.05 ± 8.04 minutes; $P = 0.0001$; Table 2).

Most patients in our series recovered successfully with no major complications; a few had slight pain or unusual sensation in the legs, and these conditions disappeared within 2–4 weeks after surgery. Some had thrombophlebitis and skin burn or recanalization after EVLA. Mild skin burn occurred in 12.16%, and no treatment was required. Other patients (9%) reported that skin burn required treatment; the discrepancy may be due to the varied manipulation of laser treatment. Presence of blood in thermal ablated veins may cause the intraluminal thrombus, and laser thermal injury can damage the surrounding tissue. It was not difficult to puncture varicose veins precisely and seal the varicose veins with laser energy. Otherwise, it could damage surrounding tissue, and cause the neuritis.

Blood extravagation was reported to occur after use of the 980-nm laser in humans[12] and animal models.[13] Bruises after thermal ablation indicate that the blood extravagates from the vessel into the surrounding tissue. In our study we observed that ecchymosis was caused by bleeding from the perforated vein. Insufficient pressure on the perforated varicose veins caused the bruising after laser ablation. The number and size of ecchymoses were associated with the number of perforated veins and the external pressure. In addition, the laser power released and the speed to retract the laser fiber could influence the incidence of vein perforation.

There is no accurate approach to measure the ecchymosis or hematoma. In our practice, the severity of ecchymosis was grouped into mild, moderate, and severe types. The incidence and severity of ecchymois in the ICLA group were less than that in the SA group, and no hematoma occurred in the ICLA group. The reasons for hemorrhage or hematoma in the SA group included no ligation of the opening end of residue of varicose veins or insufficient pressure on the legs. In addition, we found that the severity of itchiness was associated with the size of the ecchymosis and the bandage materials on the legs. More patients in the SA group complained of itchiness than in the ICLA group, usually starting around day 3 after treatment and lasting for about 1 week. The ecchymosis may not necessarily cause postprocedural pain; however, it is highly suspected to induce the itchiness after laser therapy.[15] Metabolites and decomposition of blood in ecchymosis are suspected to cause irritation.

Occlusion rates with EVLA have been reported at 98%–100%.[8,16] In our series, the occlusion rate within 4 weeks after laser ablation in both groups was 100%; however, 1 patient in the ICLA group had early recanalization of the treated branched varicose veins. This was most likely due to insufficient pressure after laser ablation. Three patients in the SA group had visible branched varicose veins; these might have been missed during stab avulsion. Thus, we emphasized and educated our patients on the significance of the compliance with postoperative compression and this could help to minimize the risk of early recanalization. In addition, energy density more than 60 J/cm is the main determinant of successful GSV ablation after laser ablation.[17] Two patients in the ICLA group had new spider veins 4 weeks after treatment. The overall 5-year recurrence of varicose veins was infrequent in the ICLA group, but higher in the SA group (5.4% versus 20%; $P = 0.022$).

The treatment of varicose veins usually occurs on the day surgery. The patients are not required to stay in the hospital in North America and Europe. However, because of the cultural belief and unfavorable medical working environment in China, most patients with varicose veins were required to be hospitalized. In addition, the medical insurance policy favors and encourages the hospitalization if patients claim the medical costs.

We acknowledge the limitations of our study. Because our investigation is based on a randomized study, after the patients were assigned to the treated group and we had to inform them of the treatment option, ICLA or SA, those patients who failed to provide written consent were excluded from this

study, and this might cause selection bias. The criteria of discharge depended on the severity of pain and the patients' consent. Thus, the discharge conditions were not standardized; this could influence the length of hospital stay. In addition, pain visual scores could be influenced by the patients' psychological status. Perhaps, this biased our results of pain scores.

In summary, we have shown that ICLA has significant advantages over SA with respect to the length of hospital stay, surgical scars, earlier return to work, and postoperative in-hospital morbidity. The long-term recurrence rate of varicose veins was less in the ICLA group than in the SA group, although there was no significant difference.

Although the ICLA procedure took longer to perform, it resulted in significantly better and earlier outcomes than SA. ICLA is superior to SA in abolishing the residual varicose veins. It is a safe, effective, and practical approach and easy to manipulate.

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