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Original Article

Hemodynamic classification and CHIVA treatment of varicose veins in lower extremities (VVLE)

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Abstract: Objective: To develop a new method of classifying hemodynamics in varicose veins of lower extremities (VVLE) and make a comparative analysis to determine the efficacy of ambulatory conservative hemodynamic correction of venous insufficiency (CHIVA) treatment. Methods: 150 cases with VVLE in our hospital were selected. Firstly, color doppler ultrasound examination was performed for each patient. Secondly, the hemodynamics of the patients were systematically divided into 6 types: I, II, III, IV, V, and VI. Lastly, complications and recurrence rate were detected to investigate the clinical efficacy, the patients were evenly divided into 3 groups which receiving different treatments: traditional surgery group, endovenous laser treatment group and CHIVA group. Results: Compared with the other two groups, patients in CHIVA group showed significant better performances on clinical efficacy, cure rate, complications and recurrence rate ($P<0.05$ and $P<0.01$). Conclusion: CHIVA treatment has significant better curative effect than traditional surgery and endovenous therapy in the treatment of varicose veins. CHIVA treatment induced less damage, quicker health recovery, high safety factor and lower complications. Thus, CHIVA treatment can be widely used in clinical restoration than general minimally invasive operations.

Keywords: Varicose veins, hemodynamic classification, CHIVA

Introduction

Varicose veins of lower extremity (VVLE) is the most common disease in vascular surgery, with the incidence as high as 15% [1]. It usually attacks long-time standing population. The main symptoms of VVLE are veins bulge, swelling, circuitous, worm like shape, obvious in great saphenous vein of shank. Middle-term VVLE may be accompanied by furfur, itching, even eczema and ulcer. Longer-term VVLE often leads to vascular pain, lower limb swelling, superficial vein thrombosis, which severely affecting the life quality and health state of patients.

The main cause of VVLE is insufficient close of valve in superficial venous system [2]. At present, clinical treatment methods mainly include traditional standard operation treatment [3] and the newly developed endovenous laser treatment, catheter coagulation therapy, etc. However, recurrence rate of traditional surgery can be as high as 20%~80% [4]. In addition, new technology of endovenous laser therapies is still based on the principle of traditional surgical treatment [5]. There is no sufficient evidence to prove their superiority.

Different pattern of reflux flow and the bypass flow leads to distinct prognosis. It needs different treatment strategies and methods of ambulatory conservative hemodynamic correction of venous insufficiency (CHIVA). Therefore, we used a new model to classify hemodynamics of varicose veins.

Materials and methods

Study subjects

Totally of 150 patients with VVLE (in our hospital from June, 2013 to February, 2015) were selected. The selecting standards were: (1) primary and unilateral VVLE; (2) 18-70 years old; (3) class C2-6 in CEAP classification system; (4) no surgery or stiffener treatment history; (5) deep venous function is normal; (6) with walk-

Table 1. VVLE Classification in the three groups

Groups	Total Number	Grade C2	Grade C3	Grade C4	Grade C5	Grade C6
Traditional surgery group	50	5	18	13	9	5
Laser group	50	5	17	13	9	6
CHIVA group	50	5	18	12	9	6

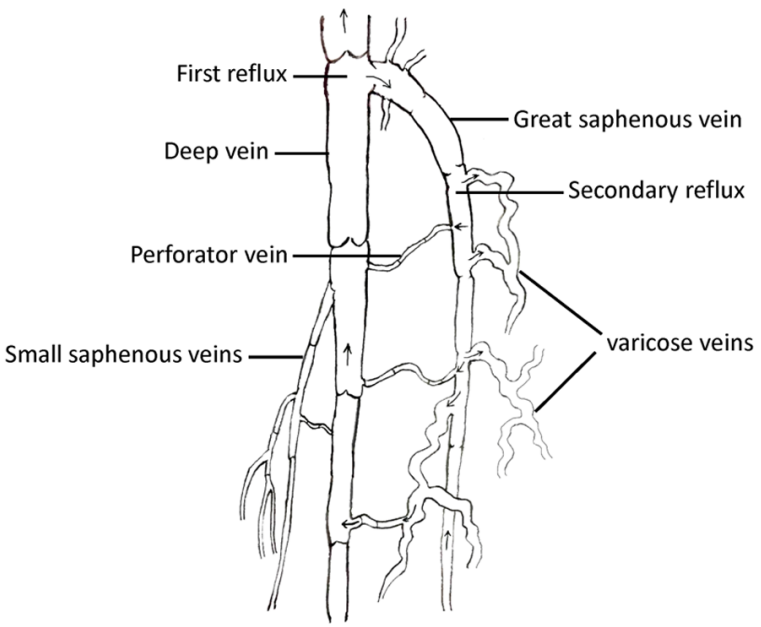

Figure 1. Schematic diagram of the Hemodynamics in VVLE.

ing ability; (7) signed the informed consent based on full understanding of grouping and treatment method. Exclusion criteria: (1) just in early stage diseases (grade C0-1); (2) no walking ability or gastrocnemius muscle dysfunction; (3) with diabetes, autoimmune diseases, malignant tumor, kidney failure, abnormal liver function, heart or lung diseases, etc.; (4) with deep vein thrombosis history; (5) suffering or suffered from psychiatric or neurological diseases; (5) unwilling to accept our grouping and study.

The patients (96 male and 54 female cases) were 25 to 69 years old (on average 46.5 ± 7.9 years), with unilateral VVLE (right limbs VVLE in 59 cases, 91 cases of left VVLE). The disease duration of the patients was 2 to 35 years (on average 15.1 ± 2.9 years).

Randomization

The voluntary patients were randomly divided into three groups with no significant difference on age, gender, disease duration and VVLE: traditional surgery group (50 cases), laser group (50 cases) and CHIVA group (50 cases). They were statistically comparable. The traditional surgery group received high ligation at saphenous vein and stripping treatment. The laser group received endovenous laser therapy. The CHIVA group received CHIVA surgery. The cure effect and recurrence rate of CHIVA group were compared with the two other groups. The VVLE situation (**Table 1**) of 3 groups was classified according to the standards of International Union of Phlebology.

Classification

Classification of VVLE has been reported. For example, according to the venous reflux pattern, Criado, et al. classified the chronic dysfunction of lower limb vein into type 1, type 2, type 1 + 2, type 3, type 4, type 2 + 4, type 5 and type 6. However, this classifying model is relatively complex and not systematic. Thus, we built a new set of hemodynamic typing in VVLE based on the combination of theory and practice in our hospital.

The venous network in lower extremity was divided into three levels: (1) First vein network locates in the deep fascia. It belongs to the deep venous system; (2) Secondary vein network lies between deep and superficial fascia. It mainly includes great and small saphenous vein and their branches, perforator veins connecting deep veins, and Giacomini vein (intersapenous vein); (3) Third vein network locates at the outside of superficial fascia. It is the main branches of saphenous vein, superficial veins between secondary veins networks. The blood flow from deep venous back to secondary vein was named the first reflux. The blood flow from secondary veins to third veins was called secondary reflux (**Figure 1**).

The classification standards were: A. whether there was first reflux; B. whether there was sec-

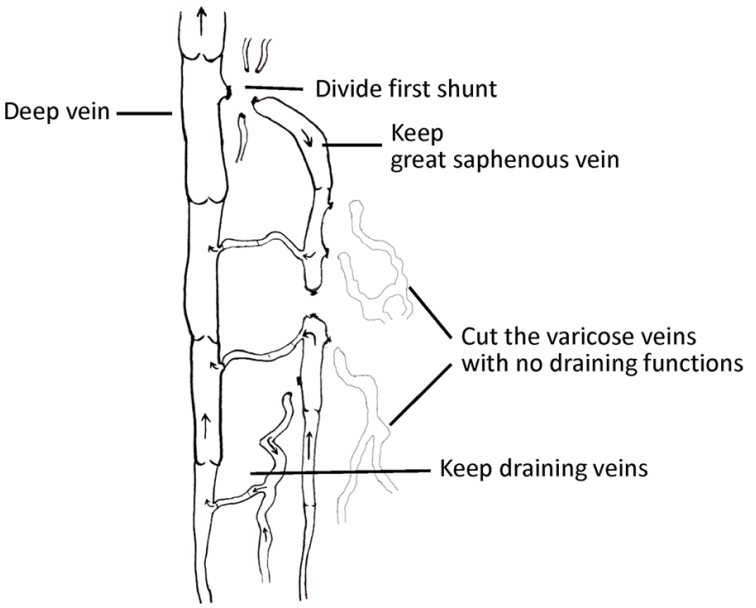

Figure 2. Schematic diagram of the CHIVA surgery.

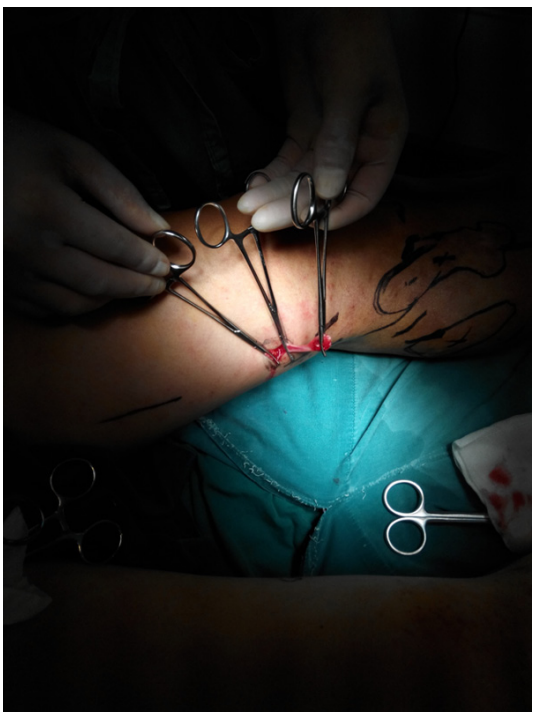

Figure 3. Stripping the secondary by pass during CHIVA surgery.

ondary reflux; C. whether there were re-entry perforator veins. Based on these standards, we classified the hemodynamics in VVLE into 6 types: Type I: first reflux + second reflux + re-entry perforator veins. Type II: first reflux + second reflux + no re-entry perforator veins. Type III: first reflux + no second reflux + re-entry perforator veins. Type IV: first reflux + no second reflux + no re-entry perforator veins. Type V: no first reflux + second reflux + re-entry perforator veins. Type VI: no first reflux + second reflux + no re-entry perforator veins or secondary veins back to deep vein. Accordingly, we classified the hemodynamics of VVLE in all 150 patients.

First of all, patients received color Doppler ultrasound examination before CHIVA operation. The device was Sequioa512 color Doppler ultrasonic diagnostic instrument, with output 23 Kw power, linear array probe and 10 MHz frequency. The standards of using measurement parameters: Gain adjustment grade was 50; probing depth was 40 mm; default setting was Vascular-LEV; scanning speed was 50 mm/s, blood flow velocity range was ± 3 m/s; the sampling line angle was 45 degrees.

Direct examination method was used. Subjects took standing position, with bilateral legs straight. Longitudinal and transverse scanning were performed. At the same time, the deep veins (including iliac vein and inferior vena cava), superficial veins and perforator and traffic were checked. Venous reflux sites need to be identified and labeled, perforator veins and communicating branches were examined. The reflux positions of veins were labeled. So did the perforator veins from superficial veins to deep veins. Parana and Valsalva test were applied to figure out the reflux mode of superficial veins, evaluate subtypes, and mark the reflux position and vein segments to be cut. At the same time, recording and drawing were performed according to the marks on patients' legs.

Therapy

Traditional surgery group: High ligation of great saphenous vein and stripping treatment were performed. Under continuous epidural anesthesia, great saphenous was found. Great

Figure 4. After CHIVA surgery.

saphenous vein and its branches was cut and ligated 0.5 cm below inguinal ligament. The stripper was inserted downward from distally end. When the promoting resistance was large, small incision was done to isolate the stripper. After the ligation of the two incision ends, the stripper were slowly withdrew. Veins were oppressed and sutured. For those varicose parts unable to use stripper, dot cut stripper was used: elevated the pathological legs, exsanguinated by bandage, excessive, pneumatic hemostat was performed about 0.08 Pa above knees, a vascular forceps was used to clamp calf, another forceps was used for stripping. After the surgery, relax the tourniquet post binding up with oppression of bandage pad. Patients were allowed to get out of bed after anesthetic effect disappearing.

Laser group: All 50 patients this group were received endovenous laser therapy. The patients lay horizontally, received epidural anesthesia and saphenous vein ligation. Great saphenous vein was punctured with 18 trocar 1-2 cm anterior superior to medial malleolus. 5F multi-use catheter was subsequently placed in antegrade. The roots of great saphenous vein were ligated. Raise the pathological limb and tried to excrete endovenous blood. Placed laser optical fiber and started the laser (Semi-Conductor Laser Therapeutic Apparatus LFK-SLT30, Leifukang) (808 nm, 16 W output power and continuous emission mode). When using the laser, laser fiber was pumped back 2-3 mm per second. At the same time, the veins were oppressed with wet and cold saline bandage on the route of pumping laser fiber, until withdrawing lase fiber and catheter. Local superficial varicose veins were stripped using line or dot pattern. After the surgery, ligation was completed by elastic bandage compression. Patients were allowed to get out of bed after anesthetic effect disappearing.

CHIVA group: Before surgery, local anesthesia was done by 1% lidocaine subcutaneous injection. During surgery, high the saphenous vein close to deep vein and the reflux perforator veins, leaving no stump. It's distal vascular was ablated for 4-5 cm. At the same time, ligated and stripped and remove 4-5 cm distal vascular in secondary reflux, and then ablated the secondary veins with no draining function in dot pattern from small cutting ends. Keep the main stem of the saphenous vein, retained the normal function of the perforator vein, and the secondary varicose veins in normal perforator veins. After surgery, ligation was completed by elastic bandage compression. Patients were allowed to get out of bed and leave operation room by walking. Patients walked for a number of hours according to doctor's advice every day, so as to promote the reflux of the superficial vein and prevent thrombosis (**Figures 2**-**4**).

Post-surgery treatment: After surgery, all patients took low molecular weight heparin for 7 days to prevent deep vein thrombosis. Antibiotics were applied according to the presence or absence of infection. Patients were further examined 1 week later, continuously wear elastic knee stocks of 30-40 mmHg pressure for at least three months, further examined and followed-up at 3, 6, 12, 18 months post-surgery.

Statistical analysis

Statistical analysis were performed by SPSS software, all data was showed by means ± SD. The statistical significance of differences was evaluated by χ^2 test or one-way ANOVA. $P<0.05$ indicated statistical significant difference.

Table 2. The comparison on surgery conditions of patients in three groups

Projects	Traditional surgery group (n=50)	Laser group (n=50)	CHIVA group (n=50)
Surgery time (min)	41.6 ± 5.4*,a	30.2 ± 3.7*	21.5 ± 4.2
Surgery incision size (mm)	24.7 ± 4.2*,a	6.5 ± 1.4	4.2 ± 2.3
Bleeding volume (mL)	36.1 ± 4.5*	30.1 ± 2.9	29.5 ± 2.5
Time of post-surgery activity (min)	35.4 ± 6.1*	31.5 ± 2.3*	0

Notes: *P<0.05 VS. CHIVA group; aP<0.05 VS. Laser group.

Table 3. Comparison on general curative effect of patients among the three groups

Groups	Total Number	Cure (%)	Recurrence (%)
Traditional surgery group	50	25 (50)*	5 (20.0)**
Laser group	50	32 (64)	2 (6.25)a
CHIVA group	50	41 (82)	0

Notes: *P<0.05 VS. CHIVA group; **P<0.01 VS. CHIVA group; aP<0.05 VS. Traditional surgery group.

Table 4. Comparison on complications of patients among the three groups

Projects	Traditional surgery group (n=50)	Laser group (n=50)	CHIVA group (n=50)
Thrombophlebitis (%)	4 (8)	3 (6)	1 (2)
Ecchymoma (%)	4 (8)	3 (6)	1 (2)
Numbness (%)	6 (12)	5 (10)	0
Phlegmon (%)	5 (10)	4 (8)	1 (2)
Other	3 (6)	3 (6)	0
χ^2	4.9859	3.1252	-
P	0.0254	0.0136	-

Results

Type statistics

96% of 150 patients showed reflux. In all reflux cases, 89% patients exist saphenous vein reflux (5% leg saphenous vein reflux in was accompanied by perforator vein reflux, 4% leg saphenous vein reflux was complicated with saphenous popliteal veins reflux), 5% were with saphenous popliteal veins, 6% were simple perforator reflux. 4% patients were without primary venous reflux, only showed local superficial varicose veins. All patients had reflux perforators flowing into saphenous vein, which were mainly located in above-knee trunk and below-knee branches in great saphenous vein, and small saphenous vein in post-shin trunk. The results of the classification were as follows: type I 91%, type III 5%, V 4%. There was no statistical difference on hemodynamics of varicose veins among patients.

Surgery performance

Firstly, the differences on surgery time, surgery incision size, bleeding volume, and the time of post-surgery activity were compared in three patient groups. Specific statistics were shown in **Table 2**. From the **Table 2**, we could see that CHIVA group was obviously superior to the traditional surgery group and laser group on each index. Secondly, the cure rate and recurrence rate in three groups were compared. CHIVA group had higher cure rate than traditional surgery group and the laser group, showing significant difference with the traditional surgery group (χ^2=3.9533, P<0.05) and no significant difference with laser group (P>0.05). In addition, CHIVA group had lower recurrence rate than other groups, showing no significant difference with laser group (P>0.05), but with significant difference on traditional surgery group (χ^2=6.7687, P<0.01). Laser group was lower than traditional surgery group, with significant difference between groups (χ^2=4.2655, P<0.05). Specific results were listed in **Table 3**.

Complications of patients

When comparing complications, such as thrombophlebitis, ecchymoma, numbness and phlegmon, etc., CHIVA was much better than traditional surgery group and the laser group, with significant difference (χ^2=4.9859, P<0.05 and χ^2=3.1252, P<0.05, respectively). Traditional surgery group was higher than laser group, with no significant difference (P>0.05). Specific results were shown in **Table 4**.

Discussion

Vein wall weakness, venous valve defect and lasting increase of superficial vein high pres-

sure were main causes of varicose veins. However, traditional surgical method generally requires the removal of all or most of varicose veins, which leads to the reduction of overall vein capacity and increase the local pressure in lower extremity veins, causing easy recurrence. In addition, general minimally invasive surgical therapy, such as catheter electric coagulation and endovenous laser burning and closing, inevitably cause vein walls ambustion and even losing elasticity, although it retaining the varicose veins. Patients with long-time standing or endovenous pressure elevation, varicose veins in patients will be very easy to recur [8, 9].

CHIVA has two important principles different from traditional operation. Firstly, through high ligation at reflux sites to block the venous reflux, it cuts off the high pressure venous reflux causing varicose veins. Secondly, it retains those varicose veins with perforator and drainage function, does not completely resect the varicose veins, so that reserved varicose vein is conducive to skin venous drainage and the recurrence of varicose veins is effectively prevent [10-12].

This study made a comparison of surgical cure effect and post-surgery recurrence among CHIVA methods and two other commonly used surgical therapies (traditional surgery and endovenous laser closure). The results demonstrated that CHIVA had better performances than traditional surgery group and laser group on surgery duration, surgery incision size, bleeding volume, post-surgery activity time, the general cure rate and recurrence rate, which proved the advantages of CHIVA method in the treatment of VVLE.

For occurrence of post-surgery complications, CHIVA group was significantly lower than the other two groups. Remarkably, it also showed the 1 case of thrombophlebitis, 1 cases of ecchymoma and 1 case of phlegmon. However, they were all cured after symptomatic treatment. By following up, we found that the patient with thrombophlebitis failed to follow the doctor's advice to keep excises such as everyday walking but mainly adopt sitting, resulting the unsmooth of blood circulation in lower extremities. The patients with ecchymoma or phlegmon did not ask for timely medical treatment after suffering from different degree of infection in surgical incision. Therefore, there were two main causes of complications occurrence after surgery. One was that the surgical incision nursing was not strict enough, leading to a certain degree of infection. They were no treated with antibiotics promptly, which caused inflammation. Another reason was that the patients could not strictly follow the doctor's advice to effective control activity time. Excessive activities and long-time standing or sitting resulted unsmooth of blood circulation in lower extremities, which cause the occurrence of thrombophlebitis or vein haematoma. These cases suggest that more attention should be paid during future clinical practice and post-surgery doctor's advice, follow up and health guidance.

In addition, since hemodynamic classification of patients is necessary before CHIVA surgery to the patient's, we propose the I-IV classification model based on reflux and reflux perforator. This model is easy and simple in the actual operation. It can figure out whether there are return flow, secondary reflux or reflux perforator. These features are conducive to the implementation of further surgery and worth clinical application in the future.

However, there are also some limitations of CHIVA surgery. For example, the high requirements on doctor's experience and ultrasonic equipment, which are not suitable for serious varicose vein patients with no walking ability. Beside, in this study and some related researches reported in the literature, there were less number of subjects and test participants, and result evaluation were not double-blind, which caused that the collected data might not fully reflect clinical practice. Therefore, it is necessary in the future clinical practice to collect more cases; use randomized controlled trials, and double blind or blind study if necessary. These efforts may further confirm the advantages of CHIVA technology, and the promoting its application.

In conclusion, combining the analysis on curative effect, cure rate, recurrence rate and post-surgery complications, etc., we discovered that CHIVA surgery were superior to other general methods (traditional surgery and endovenous laser treatment) in treating VVLE. It brings better surgery effect, smaller surgery incision, quicker recovery, higher safety factor and lower recurrence rate.

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Disclosure of conflict of interest

None.

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