Clinical Observation of Foam Sclerotherapy Combined with Ligation of Great Saphenous Vein in the Treatment of Great Saphenous Varicose Veins

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ABSTRACT

Objetive: This study aims to compare the curative effect of ultrasound guided foam sclerotherapy in combination with ligation of great saphenous varicose vein with stripping of great saphenous vein in the treatment of great saphenous varicose veins.

Methods: 103 cases of patients with great saphenous varicose veins were randomly divided into two groups, group A 54 cases underwent high ligation of great saphenous vein and stripping of the saphenous vein, group B 49 cases performed high ligation of great saphenous vein combined with foam slcerotherapy, and the operation time, postoperative recovery time, the duration of pain, cost of surgery, incidence of complications, quality of life, and the recurrence rate were compared.

Results: The operation time, postoperative activity recovery time and duration of pain of group B was lower than that of group A ($P < 0.05$). There was no obvious difference of surgery expenditure between the two groups ($P = 0.246$). At three months after operation, life quality evaluation was statistically significant different between two groups of patients ($P < 0.01$) according to the aberdeen varicose vein questionnaire (AVVQ). At six months after operation, the cure rate of group B was 87.8%, and the cure rate of group A was 92.6%.

Conclusions: Compared with stripping of great saphenous vein, ultrasound guided foam sclerotherapy in combination with great saphenous vein ligation can shorten operation time, and decrease the postoperative discomfort, but which has lower curative rate than the latter.

Keywords: foam sclerotherapy, great saphenous, ligation of varicose veins, stripping of varicose veins

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INTRODUCTION

Great saphenous varicose veins is very common clinical disease, long term venous sedimatation can not only cause circuitous expansion in the venous wall and produce lower extremity bilges, swelling and heaviness, but also will cause the skin pigmentation, then skin ulcer, which may seriously affect the quality of patients' life (1). Since the classic iatrotechnique described by Keller (2) 100 years ago that remove of the saphenous vein with an inverting stripping combined with division of its tributaries, this method has been continuously improved. With the deepening of the concept of minimally invasive medicine, the treatment of this disease is becoming more and more pursuit of minimally invasive, including improvement of conventional surgery, such as restrictive stripping of the great saphenous vein (GSV) trunk and pin avulsion of varicose veins under knee, and the rise of the various new technologies such as intracavity laser, sclerotherapy, radio frequency technology, and so on (3-5). Especially, it should be paid attention that, in recent years, the foam sclerotherapy showed good clinical benefit in the treatment of great saphenous varicose veins, such as little trauma, quick recovery, low medical cost (6,7), but also had the problem of high recurrence rates (8). To overcome its drawback, foam sclerotherapy carried out with combination of high ligation of GSV (7). This hybrid therapy was proved to minimize the recurrence of varicosities in the western peoples. However, patients with GSV varicosities in China always present more serious manifestations, such as more varicose briquettes and more complications. Therefore, compared to traditional venous stripping, whether will the hybrid therapy have more clinical benefits? This paper designed a prospective randomized controlled trial to answer the question.

MATERIALS AND METHODS

General information

From January 2010 to July 2010, patients with simple great saphenous varicose veins (SSVV) in vascular surgery of our hospital were included, and which performance were limb bilges, swollen, circuitous and expansion of great saphenous vein running area, even forming mass, sometimes appearing limb edema, apparently during erect. All of the patients had not been treated before. According to treatment method, the patients were randomly divided into group A and group B; group A included 54 cases of patients, 30 cases of male, 24 cases female, aged 37-75 (mean 49.6 + / - 3.8 years), the course of 5 ~ 34 years (average 16.3 + / - 2.7 years), 33 cases of unilateral limbs, 21 cases of bilateral lower extremities, which were performed high ligation of great saphenous vein combined with great saphenous stripping operation; group B included 49 cases patients, 31 cases of male, 18 cases of female, aged 27 ~ 77 (mean 52.3 + / - 4.2 years), the course of 2 ~ 29 years (mean 13.2 + / - 3.3 years), 23 cases of unilateral limb, 26 cases of bilateral lower limb, which were performed high ligation of great saphenous vein combined with form sclerotherapy. There was no statistical difference in terms of gender, age, medical history, and patients' condition between the two groups of the patients ($P > 0.05$), which were comparable, and all were confirmed of no lower extremity unobstructed and reflux by preoperative ultrasonic B examination. This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Zhengzhou University. Written informed consent was obtained from all participants.

Operation time

The patient's leg and groin were prepped with aqueous povidone iodine and draped with the entire leg exposed from above the groin to just above the ankle. After groin dissection, division of tributaries and flush ligation of the sapheno-femoral junction (SFJ), the GSV was divided and canulated distally using a 5 Fr angiography catheter at a point approximately 10cm distal to the knee. Ultrasound imaging (Sonosite 180®, Sonosite Inc, Bothell, WA, USA) was used to position the catheter and subsequently to guide tumescent infiltration of local anaesthetic (40mls 0.5% Bupivacaine with adrenaline diluted in 500ml of 0.9% Saline solution) along the length of the GSV/catheter. This achieved the dual effect of compressing the vein and decreasing its capacity as well as post operative analgesia.

High ligation of great saphenous combined with great saphenous stripping (group A): The running of varicose vein and serious lesion area was marked preoperatively; after skin preparation, dissection of groin, division of the trunk and tributaries of the great saphenous, dual high ligation and incision of the trunk of the great saphenous was performed at 0.5cm to the saphenous-femoral joint; making a 1cm incision 1-2cm upper to the malleolous, the proximal vein was dissected; a metal stripper being inserted into the proximal vessel cavity, passing through the root of the dissected great saphenous, slowly dragging from top to bottom, the great sapheneous was stripped off. At the same time, the great sapheneous was compressed for five minutes to make the wall of vein closure; the disperse crural varicose was performed pin stripping.

High ligation of great saphenous combined with foam sclerotherapy (group B). Preparation of the foam: 2ml 1% Lauromacrogol injection (Shanxi Tianyu Pharmaceutical co.,

LTD) was fully mixed into 10ml sclerosing foam with 8ml air or CO_2 for immediate (Tessari method) usage, which should be homogeneous, sticky, and no visible single bubble.

Operation procedure

After ligation of the sapheneous-femoral valve, 6ml sclerosing foam was injected to proximal great sapheneous with10ml syringe, and with slowing injection of sclerosing foam, it was visible the blue color blood in the varicose vein gradually regressing with the entering of the foam. If necessary, the varicose vein should be slowly massaged and the medium varicose vein would turn into sclerosing cord within 2 min pressure; the residual trunk without sclerosing foam should apply injection of the sclerosing foam after incision, at the same time, any perforating veins were protected under ultrasound to prevent foam entering the deep venous system.

Anesthesia

All participants were performed general anesthesia, elevated limbs, and applied compression bangdage dress after surgery, which were changed for elastic stocking after 24 hours, and all patients were encouraged early ambulation.

Postoperative treatment

All patients were followed up 3 months and 6 months post-operatively. The follow-up included history, physical examination and color duplex venous ultrasound. History and physical examination were aimed at detecting any complication. All patients with residual

varicose in both groups received additional foam sclerotherapy treatment. The follow-up evaluation at 3 months included classification using the CEAP systems and the completion of the AVVQ.

Statistic analysis

Using SPSS18.0 statistical software, the measurement data were expressed as mean ± standard deviation, which were compared with t-test, and the enumeration data were compared with the exact probability method and rank-sum test. $P \leq 0.05$ was taken as statistically significant.

RESULTS

Operation time

As shown in table, the operation time of group A was 42-105 minutes, of group B was 25-60 minutes, which had significant difference ($P < 0.01$).

Length of time recovery normal physical activity

As shown in table 1, group A and group B respectively recovery normal physical activity at 4-15 days, and 3-7 days after operation, which had significantly difference.

The postoperative pain

As shown in table 3, 67.3% (33/49) patients of group B didn't taken analgesic medicines, while only 18.5% (10/54) patients of group A didn't taken analgesic medicines, 42.6% (23/54) occasionally took analgesic medicines (no more than 3 times), and 38.9% (21/54) ever took the analgesic medicines more than 3 times. There was significant difference between the two groups.

Incidence of complications

As shown in table 1, there were 10 cases of group A patients and 8 cases of group B patients occurred the complications, and the detail was shown in table 2. There was no deep vein thrombosis, pulmonary and cutaneous necrosis in both groups.

Expenditure of the hospitalization

As shown in table 1, the expenditure of hospitalization of group A was 3524-4289 yuan (mean 4025 yuan), and of group B was 3396-4578 yuan (mean 3978 yuan), which has significant difference ($P = 0.246$).

Follow up

All patients completed the AVVQ for evaluating the influence of the treatment on the patients' life quality. A surgeon and a vascular surgical nurse observed the complications of the patients. After treatment, all the limb varicose veins, acid biges, edema, fatigue of the two groups' patients disappeared. 3 months after operation, AVVQ life quality evaluation showed

that group A decreased from 23.5 to 12.3 (40%), group B decreased from 15.4 to 9.2 (43%), and there was significant difference between the two groups ($P < 0.01$). The ultrasound assessment of the great sapheneous showed that, 3 months after operation, there were 4 patients of group A and 5 patients of group B who need further sclerotherapy for completely obliteration of the great sapheneous. 6 months after operation, 4 cases (7.4%) in group A had not been completely cured, with the cure rate of 92.6%, and 6 cases (12.2%) need the sclerotheray once again, with the cure rate of 87.8%.

DISCUSSION

The previous evidence-based medicine considered that the surgery is the first choice for treating the great saphenous varicose vein (8,9). Limit avulsion of the trunk of the great sapheneous is the improvement of the traditional operation, which may reduce the injury of saphenous nerve during the long segment stripping of the saphenous vein. But this method still has relative great trauma, especially when the varicose vein is of large range and deep, the stripper is difficult to insert and strip, so as to prolong the operation time and increase the complexity of the operation (10). And, after stripping, the hematocele in the tissue space, even tissue injury may be caused, which is the important reason of postoperative leg pain or discomfort, and may cause the average hospitalization relative long (11,12). Therefore, the traditional surgery is challenged by a variety of minimally invasive technology.

Sclerotherapy, that is to inject the chemical sclerosing agent to make intracutaneous, subcutaneous, and (or) intra-fascial varicose vein, and infra-fascial varicose vein of the

veneous malformation patients develop the venous wall secondary inflammation. At the same time, which is local compressed, after a period of time, the granulation tissue, and secondary fibrosis may form, and grow in the collapse vein lumen, then eventually forming fibrous stripes, as to achieve the aim of treatment the varicose vein (13,14). But the previous liquid sclerosing agents had not been used for large dosage, side effects, and high recurrence rate, which had been replaced by wide used foam sclerosing agent.

The principle of the foam slerosing agent is to mix the denaturant (sclerosing agent) with proper amount of gas, to generate the micro-foam to be injected into the varicose vein. Because the vein itself exists reflux, and the gas foam has certain air embolism, it makes the gas foam being difficult to move into the deep vein with the blood flow in the varicose vein, and the sclerosing agent can cause the endothelial cells damage, vasospasm, formation of mural thrombus, vascular closure, eventually formation of fibrous cord and gradually soften (15-17). The mixture of the gas itself may reduce the dosage of the destructive sclerosing agent and increase the contact area of the sclerosing agent with the vessel wall (18), while ultrasound guided sclerotherapy enable the injection more safe and accurate, and reduce the complication. The safety and accuracy of this method has been recognized in the Second European Foam Sclerotherapy Coordination Meeting (19).

Compared with the traditional stripping method, the foam sclerotherapy has the advantages of shortened operation time and postoperative hospital stay, reduced pain, effective and cosmetic function. The main disadvantages the foam sclerotherapy are in need of closely follow up and repeated injection due the relatively high recurrence rate (20,21). Bountouroglou *et al* proposed that the combination of the traditional surgery and the foam

sclerotherapy, and the ligation of the great saphenous can reduce the recurrence rate of the varicose vein in the maximum extent (7), because it is the main reflux point of the low extremity veins.

This study showed that high ligation of great saphenous combined with the foam sclerotherapy (group B) had obviously shortened operation time than the high ligation of great saphenous combined with great saphenous stripping (group A), which was consist with the previous studies. Meanwhile, the former showed obviously earlier recovery normal physical activity, and had less patients in need of postoperative analgesics than the latter, and which had small incision for cosmetic effect. This is due to that the high ligation of great saphenous combined with the great saphenous stripping need multiple incisions and multiple stripping the trunk to complete the operation, has large intraoperative blood loss, big trauma, long recovery time and more obvious postoperative pain. The shortened operation time may further shorten the length of hospital stay. There was significantly difference between the two groups. The analysis of life quality showed that, compared with the stripping group, the high ligation of great sapheneous combined with the foam slcerotherapy obviously reduced the postoperative discomfort.

The expenditure of operation of foam sclerotherapy group patients also was lower than the stripping group, although there was no significant statistic difference. The complications of the two groups' patients both were less, and there was no serious complication. It is similar with other research that the occlusion rates of the two groups were same, but the AVVQ classification of the foam sclerotherapy group obviously reduced, suggesting that the high ligation of the great sapheneous combined with the foam slerotherapy have the advantages of

exact curative effect, simple operation, less trauma, slight pain, less complication, and quick recovery, which have excellent clinic prospect and can be used as a update treatment method for varicose vein.

However, for the patients with large varicose briquettes and (or) sever complications, such as extensive pigmentation and ulcers, this hybrid procedure should be carefully applied, because the varicose veins tend to be sclerosed, and the sclerosing foam is easier to penetrate into the subcutaneous tissues and exacerbate the skin changes. In our study, 2 cases were observed exacerbated complications after the foam sclerotherapy.

To sum up, high ligation of great sapheneous combined with foam sclerotheray is a kind of new treatment technology, which can shorten the operation time, reduce intraoperation bleeding, shorten the postoperative recovery, and reduce the operation expenditure.

Conflict of interest

All authors have no conflict of interest regarding this paper.

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Table 1: Comparison of each index of the two groups' patients

	Average operation time (minutes)	Time of recovery normal work (day)	Cases of postoperative pain	Cases of complications	Average hospitalization expenditure (Yuan)	Total cases
Group A	85±15	8±1.2	44	10	4025	54
Group B	45±12*	4±0.9*	16*	8	3978	49

*P<0.05

Table 2: Comparison of postoperative complication

	Group A	Group B
Groin infection	1	0
Groin hematoma	2	0
Saphenous nerve injury	3	0
Thrombophlebitis	1	5
Skin pigmentation	2	3
Urinary retention	1	0

Table 3: Comparison of postoperative pain of the two groups'patients

	No analgesic medicine	Use analgesic medicine	
		≤3 times	>3 times
Group A	18.5% (10/54)	42.6% (23/54)	38.9% (21/54)
Group B	67.3% (33/49)	28.6% (14/49)	4.1% (2/49)