Comparison of high ligation and stripping of the great saphenous vein combined with foam sclerotherapy versus conventional surgery for the treatment of superficial venous varicosities of the lower extremity

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Abstract: The aim of this study was to compare the results of high ligation and stripping of the great saphenous vein (GSV) trunk combined with foam sclerotherapy with conventional surgery for the treatment of superficial venous varicosities of the lower extremity. One hundred and thirty-eight patients with primary or secondary superficial venous varicosities of the lower extremity were included. 60 underwent conventional surgery and 78 were treated with high ligation and stripping of the GSV trunk and foam sclerotherapy of GSV branches, spider veins, and reticular veins. Surgical time and amount of bleeding of single limb, recurrence of varicose vein, complications and patient satisfaction were recorded. Compared with the conventional surgery group, the GSV trunk stripping and foam sclerotherapy group had a significantly lower surgical time (P < 0.05), amount of bleeding and duration of hospital stays (P < 0.01). No statistically significant difference with respect to the wound infection, local discomfort, postoperative recurrence rates of varicosity and patients satisfaction score was observed (P > 0.05). GSV trunk stripping and foam sclerotherapy group at a 6 months of follow up had a higher recurrence rate of varicosity as compared to the conventional surgery group (P < 0.05). High ligation and GSV trunk stripping combined with foam sclerotherapy prior to conventional surgery for patients with superficial venous varicosities of the lower extremity with a shorter surgical time, fewer bleeding, duration of hospital stays and higher patient satisfaction scores.

Keywords: Vascular diseases, foam sclerotherapy, varicose vein, superficial venous varicosities, stripping

Introduction

Varicose veins have an overall prevalence of between 20 and 60%, and approximately 25% of the adult population have at least one varicose vein [1]. This condition is often associated with great saphenous vein (GSV) reflux [2-4]. The disease has a substantial impact on quality of life, as well as on the resources and budgets of healthcare systems [5].

Treatment of varicose veins is considered appropriate by the majority of vascular surgeons if the veins are symptomatic [6]. Common symptoms attributable to varicose veins include poor cosmesis (cosmetic appearance), ache and itching. Less common problems include hemorrhage (bleeding) and thrombophlebitis (inflammation of the vein wall with associated blood clot) [7].

For many years, ligation of the saphenofemoral junction (SFJ), stripping of the great saphenous vein (GSV) and multiple avulsions is considered to be the standard treatment for varicose veins [8]. The rate of recurrence of varicose veins after 5 years has been reported to vary from 20% to 80% [9]. In the past decade, alternative treatments such as endovenous ablation of the GSV with laser (EVLA), radiofrequency ablation (RFA) and foam sclerotherapy have gained popularity [10]. Despite the prevalence of varicose veins and the vast numbers of people being treated, the criteria for each of the various treatments are not well defined. Furthermore, there is no general consensus over which intervention is the most effective [11-14].

The aim of this study was to compare the results of conventional surgery with high ligation and stripping of GSV trunk combined with foam...
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Materials and methods

The study was approved by the ethics committee of Tianjin Hospital, China, and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all subjects.

Patients

Between 2010 and 2011, a total of 138 patients (153 limbs) with primary or secondary superficial venous varicosities of lower limb at C4-C6 stage and underwent surgical treatment at Tianjin Hospital in Tianjin were included in this study. The patients consisted of 29 males and 109 females. The average age was 53.2 years (range, 38-69 years). Of the 138 patients, 60 underwent conventional surgical interventions (group A) including high ligation and stripping and the remaining 78 were treated with high ligation and stripping of the GSV trunk combined with foam sclerotherapy of GSV branch (group B). The difference between group A and B was the treatment of the branch of the GSV. All patients treated in this study were managed by experienced surgeons. At the time of operation patients were randomized assigned to one of the two groups. Neither of the patient nor the vascular laboratory staff was told of the operative allocation.

Conventional surgery group

In the convention stripping group (60 cases), patients received epidural anesthesia, lumbar anesthesia or combined spinal-epidural anesthesia. The skin incision (2-3 cm) paralleled to dermatoglyphs was made with a proximal oblique incision in the groin and a distal transverse incision in the medial malleolus. High ligation of GSV was performed and 5 main branches of proximal end of GSV were cut off. Then, GSV trunk stripping was performed from distal to proximal using a stripper (Gamida Tech, France) followed by 15 min of compression of the tunnel. Thereafter, branches of GSV were stripped and communicating branches was ligated. Patients were discharged on the day of operation or the first postoperative day. All patients wore elastic compression stockings immediately after injection. Patients continued wearing compression stockings during the day and night, until 2 weeks after treatment.

Stripping of GSV trunk combined with foam sclerotherapy

In group B, patients underwent GSV trunk stripping and foam sclerotherapy with lauromacrogol. Skin incision was performed in the same way as in the conventional surgery group with a proximal incision in groin and distal incision in the medial knee joint. In group B, the stripper was used to strip the GSV trunk. After the compression of tunnel, foam injection sclerotherapy under ultrasound control was performed. The sclerosing foam was prepared using the Tessari method [16], with two syringes and a three-way stop-cock. Sclerosing foam was pre-

<table>
<thead>
<tr>
<th>Sex ratio (male/female)</th>
<th>Age ± 95% CI</th>
<th>History of disease</th>
<th>Hyperpigmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>12/48</td>
<td>53.83 ± 16.28</td>
<td>16.13 ± 8.01</td>
</tr>
<tr>
<td>Group B</td>
<td>17/61</td>
<td>52.76 ± 14.84</td>
<td>15.05 ± 7.76</td>
</tr>
</tbody>
</table>

Statistical value: $t = 0.365$, $t = 0.801$, $\chi^2 = 0.126$; $P$ value: $P > 0.05$, $P > 0.05$, $P > 0.05$

Group A, conventional surgery group; Group B, high ligation and stripping of the great saphenous vein combined with foam sclerotherapy.
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pared with the double-syringe technique, applying a 1:4 ratio of sclerosant: air. One syringe was filled with 2 ml 1% lauromacrogol injection and the other syringe with 8 ml air. Air and liquid lauromacrogol were mixed through multiple passages between the two syringes using the stopcock as a connector. Thus the liquid lauromacrogol is mixed with air, becoming dense foam. During the process of the foam sclerotherapy, 1-2 ml of sclerosing foam was injected into the marked branch of varicosity through multiple sites with a 3 cm distance between the injection points. After the injection, 10-20 ms compression was administered. When all marked varicosed vein was injected with sclerosing foam, elastic bandage was used post-sclerotherapy treatments were performed in the same way as in the surgery group.

Follow-up and medical evaluation

Intraoperatively, surgical time and amount of bleeding of single limb was recorded. In addition, postoperative complications were also recorded. All patients underwent digital photograph prior to surgery, during surgery and 6 mongths or 180 days postoperative follow-up. Patients were asked to fulfill the satisfaction survey: Very dissatisfied, (1 score); dissatisfied (2 scores); mild satisfied (3 scores); satisfied (4 scores); very satisfied (5 score).

Statistical analysis

Statistical analyses were performed by using PASW Statistics 18.0, version 18.0.0 (SPSS; SPSS, Chicago, IL). Numerical data were expressed as means ± standard deviation and were compared using t tests. Qualitative data were expressed as frequency or percentage and were compared using χ² tests. Differences were considered statistically significant when P < 0.05.

Results

The detailed clinical characteristics of the patients are shown in Table 1. There were no statistically significant differences with respect to patients stratification scores between the groups (P > 0.05). The surgical time in the GSV trunk stripping and foam sclerotherapy group was significant shorter than the conventional surgery group (P < 0.01). Similar significant difference with respect to the amount of bleeding and duration of hospital stays was observed in the foam sclerotherapy group as compared to the conventional surgery group (P < 0.01) Table 2.

Postoperatively, discomfort symptom or signs of lower limbs (such as hyperpigmentation, pain) of patients in both groups was greatly improved (Figures 1 and 2). One case in conventional surgery group progressed to wound infection in the groin and recovered after anti-inflammatory therapy. Postoperative recurrence of varicosity was noted in 1 case in the conventional surgery group and 3 cases in the foam sclerotherapy group (P > 0.05). During the 6 months of follow up, recurrence of varicosity was observed in 17 person-times in the conventional surgery group and 33 person-times in

Figure 1. Clinical symptom of lower extremity in a patient in the conventional surgery group. A. Before surgery; B. After surgery.

A

B
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Figure 2. Clinical symptom of lower extremity in a patient in the GSV stripping combined foam sclerotherapy group. A. Before surgery; B. After surgery.

Table 2. Surgical time and the amount of bleeding of single limb, duration of hospital stays, and patients satisfaction scores in two groups (means ± SD)

<table>
<thead>
<tr>
<th></th>
<th>Surgical time (min)</th>
<th>Amount of bleeding (ml)</th>
<th>Duration of hospital stays (days)</th>
<th>Satisfaction score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>89.81 ± 12.56</td>
<td>57.80 ± 17.54</td>
<td>11.33 ± 4.56</td>
<td>4.00 ± 0.84</td>
</tr>
<tr>
<td>Group B</td>
<td>61.87 ± 7.02</td>
<td>45.81 ± 6.08</td>
<td>7.55 ± 3.06</td>
<td>4.17 ± 0.76</td>
</tr>
<tr>
<td>Statistical value</td>
<td>t = 19.508</td>
<td>t = 8.114</td>
<td>t = 11.107</td>
<td>t = 1.215</td>
</tr>
<tr>
<td>P value</td>
<td>P &lt; 0.01</td>
<td>P &lt; 0.05</td>
<td>P &lt; 0.05</td>
<td>P &gt; 0.05</td>
</tr>
</tbody>
</table>

Group A, conventional surgery group; Group B, high ligation and stripping of the great saphenous vein combined with foam sclerotherapy.

Table 3. Outcome of surgical treatment in two groups

<table>
<thead>
<tr>
<th></th>
<th>Wound infection</th>
<th>Local discomfort</th>
<th>Postoperative recurrence</th>
<th>Recurrence at postoperative 6 months (person-times)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>1</td>
<td>6</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Group B</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
<td>Statistical value</td>
<td>$\chi^2 = 1.288$</td>
<td>$\chi^2 = 3.033$</td>
<td>$\chi^2 = 0.542$</td>
<td>$\chi^2 = 4.019$</td>
</tr>
<tr>
<td>P value</td>
<td>P &gt; 0.05</td>
<td>P &gt; 0.05</td>
<td>P &gt; 0.05</td>
<td>P &lt; 0.05</td>
</tr>
</tbody>
</table>

Group A, conventional surgery group; Group B, high ligation and stripping of the great saphenous vein combined with foam sclerotherapy.

Table 2 shows that the surgical time, amount of bleeding, duration of hospital stays, and satisfaction scores were significantly different between the two groups (P < 0.01, P < 0.05, P < 0.05, P > 0.05, respectively). These data were given in Table 3.

Discussion

Great saphenous vein varicosities are frequently-occurring diseases in clinics, mainly caused by defective valves in the veins, weakness of the walls of the veins or continuous increased intravenous pressure. Not timely treatment of great saphenous vein varicosities is easy to result in various complications such as superficial thrombophlebitis of the lower extremity, infection. High ligation and stripping of the GSV is currently most common used and effective method for varicose veins [17]. However, due to numerous surgical incisions, high ligation of GSV and point-form-stripping (PFS) remains challenges the medical workers. Foam sclerotherapy can be used as first-line therapy for telangiectasis and small varicose veins and supplementary therapy for large varicose veins [18]. In recent years, alternative treatments has become into practice. However, there is no general consensus over which intervention is the most effective. In our hospital we treated 138 patients with great saphenous vein varicosities, using GSV trunk stripping and sclerotherapy with foam of lauromacrogol. The
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procedure produced good clinical results which allow smaller incisions and less tissue trauma, blood loss, duration of hospital stays and shortened postoperative recovery.

In this study, 5 ml syringe connected with 5-gauge needle was used because it is easy to adjust the needle point direction and the position of the needle tip and improve the success rate of puncture blood return. During the process of injection, dispersion foam can be noted in the blood vessel, and the flow distance is about 3 cm. If blood return cannot be extract, multiple sites of paravenous injection can be applicable to block the vein. In our series, no postoperative skin ulcer was observed. In our study, the maximum dosage of liquid sclerosing agent of single limb was 10 ml, and the foam injection volume of each site was within 2 ml. Postoperatively, no discomfort symptoms such as deep venous thrombosis, choking sensation in chest, asthma, dry cough was observed. In clinical observation, foot ulcer can also be well cured by sclerosing agent. After blocking the adjacent veins surrounding the ulcer using foam sclerotherapy with lauromacrogol, sclerosing agent was injected into the surrounding area of the communicating branch of the ulcer which can accelerate the process to heal the ulcer.

In the present study, the GSV trunk stripping and foam sclerotherapy group had a more advantage in terms of surgical time, blood loss, duration of hospital stays as compared to the conventional surgery group. These findings suggest that patients receiving stripping of GSV combined with foam sclerotherapy were more likely to have a satisfactory result on clinical assessment.

Complications are inherent to any invasive technique and may occur following both surgical treatment and foam sclerotherapy. The complications observed in our patients treated surgically were similar to those reported in the published literature, but no severe complication occurred in the two groups. Suture dehiscence affected almost half of our patients in the surgery group, a finding that can be explained by the strictness adopted in the present analysis for the assessment of complications, especially those related with the healing of incisions [14]. A previous study [19] has identified post-sclerotherapy thrombophlebitis and consequent hyperpigmentation as the most frequent complication associated with foam sclerotherapy. In an earlier publication, 20 cases of chemical thrombophlebitis were diagnosed, of which 15 required aspiration drainage [20]; the remaining five cases improved spontaneously in 30 days, forming a fibrous cord. Hyperpigmentation, however frequent, is of little importance because patients with thrombophlebitis were already affected by cutaneous and subcutaneous disorders such as hyperpigmentation and lipodermatosclerosis. Regarding the risk of thrombo-embolism, previous studies [21] have shown that the foam reaches the right ventricle easily, with no significant complication. In our study, discomfort symptom or signs of lower limbs (such as hyperpigmentation, pain) of patients in both groups was all greatly improved. One case in conventional surgery group progressed to wound infection in the groin and recovered after anti-inflammatory therapy. Postoperative recurrence of varicosity was only noted in 1 case in the conventional surgery group and 3 cases in the foam sclerotherapy group. During the 6 months of follow up, recurrence of varicosity was observed in 17 person-times in the conventional surgery group and 33 person-times in the GSV trunk stripping and sclerotherapy group. The frequency of recurrent varicose veins was significantly different between the groups.

Conclusion

The finding of our study showed that for patients with primary varicose veins foam sclerotherapy combined with high ligation and great saphenous vein stripping was less tissue trauma, blood loss, and duration of hospital stays and resulted in a better overall outcome compared to conventional surgery. Further studies involving homogeneous samples and prospective randomized control study with large number of patients are still needed to confirm our results.

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Disclosure of conflict of interest

None.

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