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Application of the Trivex system in the treatment of primary severe superficial varicose veins of the lower extremity



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ABSTRACT

Purpose: The aim of this study was to evaluate the clinical effects of the Trivex system in the treatment of primary severe superficial varicose veins of the lower extremity and compare Trivex to the point-form-stripping combined with foam sclerotherapy (FS).

Methods: A total of 64 patients (35 females, 29 males; mean age, 57 ± 11 years [range, 29–79 years]) with primary severe superficial varicose veins of the lower extremity involving 64 legs were included between October 2015 and July 2019. The maximum diameter of the vein branches was >20 mm, which appeared to be cystic dilatation and forms large-scale in the crus or the thigh. All patients underwent high ligation and endovenous laser ablation or stripping of the trunk under general anesthesia. The surgical time, pain/phlebitis, number of incisions, amount of bleeding, recurrence of varicose vein, incidence of surgical site infections (SSIs), satisfaction score, and improvement in clinical symptoms were evaluated respectively with the patients in two groups: Group A, with patients who underwent treatment with the Trivex system, and Group B, patients who underwent treatment by point-form-stripping combined with FS.

Results: All procedures were performed successfully. The average operative time in Group A was 56 ± 11 min, whereas that of Group B was 90 ± 33 min, which was a significant difference ($p < 0.05$). Group A patients felt little pain after surgery, whereas in Group B the level of pain peaked on postoperative day 30, mostly due to thrombophlebitis after FS. There was no recurrence of varicose vein was observed in any patient, however, there were some residual effects in Group B, including the amount of bleeding volume, in-hospital stays, pain/phlebitis, and number of incisions ($P < 0.05$). There were no significant differences with respect to SSIs, improvement in clinical symptoms, and satisfaction scores observed ($p > 0.05$).

Conclusions: This study shows that patients benefited from both treatment options. However, primary severe superficial varicose veins of the lower extremity treated with the Trivex system suffered less pain with fewer incisions than severe branches treated with the point-form-stripping combined with foam sclerotherapy (FS). In summary, the Trivex system is a suitable treatment prior to point-form-stripping combined with foam sclerotherapy (FS) for those who demand a high level of appearance, and especially for young patients, the Trivex system is recommended.

Introduction

Superficial varicose veins (VVs) of the lower extremity are a common vascular disorder that seriously affects the quality of life. The reported prevalence of VVs varies across geographic locations and between sexes, being estimated at approximately 10–15% in male subjects, and around 20–25% in females in the City of

Edinburgh (participants aged 18–64 years)¹; another study reports

the incidence at approximately 26% of the adult population.² Superficial VVs of the lower extremity are divided into primary and secondary VVs, and here we talk about primary VVs which are associated with the great saphenous vein (GSV) and/or the small saphenous vein (SSV) reflux.³ With medical advances, there are more and more surgical options available in clinic for the trunk of the GSV, including high ligation and stripping, endovenous laser ablation (EVLA), and endovenous radio-frequency ablation (RFA). For branches of the GSV, treatments include

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foam sclerotherapy (FS), hook phlebectomy, and point-form-stripping have been widely used in clinic. A new technique, using the Trivex system, received early reports that it was a safe, effective surgical device,^{4–7} however, there are few published reports about application of Trivex system. Here, we report the results of the application of the Trivex system in the treatment of primary severe superficial VVs of the lower extremity in our center over nearly four years.

Materials and methods

The study was approved by the ethics committee of First Affiliated Hospital of ShenZhen University, ShenZhen, China, and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all subjects. A total of 64 patients (35 females and 29 males; mean age, 57 ± 11 years [range, 29–79 years]) with primary severe superficial VVs of the lower extremity were included between October 2015 and July 2019. The maximum diameter of the vein branches were >20 mm, and they formed in large-scale in the crus or/and the thigh. The 64 patients were divided into two groups randomly and underwent treatment with the Trivex system (Group A) and point-form-stripping combined with FS (Group B) for VV branches. All patients underwent high ligation and EVLA or stripping for the trunk of the GSV under general anesthesia or spinal anesthesia. All operations were performed by one vascular surgeon who is a general practitioner in our institution according to a standard protocol. The indications for surgery included lower extremity pain, pigmentation, heaviness, itching, superficial phlebitis, swelling, tiredness, and healed ulcer. The saphenous reflux was confirmed by venous duplex ultrasound (US) with a reverse flow for ≥ 0.5 s, while acute or chronic deep venous thrombosis (DVT), deep venous insufficiency, and iliac vein/postcava stenosis or occlusion were excluded by clinical examination combined with US or ascending venography; The CEAP (clinical manifestations, etiological factors, anatomical distribution, and pathophysiological findings) clinical classification was used to grade the varicosities.⁸ In this study, the CEAP classification of all patients were at the C2–C5 stage and there was no therapy with elastic compression stockings or other treatment before the surgery.

Trivex system group

In the Trivex system group, general or spinal anesthesia was administered to the patient, the trunk was treated with high ligation and EVLA or stripping, and the branches were treated using the endoscopic Trivex System (LeMaitre Vascular Inc., Burlington, MA USA). The system was designed to follow the natural skin lines of about 3 mm in size to obtain the most cosmetically appealing result, with the incisions located strategically to maximize vein cluster removal within the instrumentation arc and the endoscopic instrumentation alternated through the incisions to further minimize the number of incisions needed. The irrigation-illumination device was inserted into the first incision with tumescent anesthesia (3 L of 0.9% normal saline solution with 150 mL of 1% lidocaine and 6 mL of 1:1000 epinephrine) properly filling the area by a controlling pedal to keep the VVs clearly visible; the skin was held taut and the change in the direction of the resection in the process to prevent skin penetration. The oscillation frequency of the suction and morcellation was 800 to 1200 rpm. According to the range of the VVs, 2 to 3 additional incisions were created to ensure complete removal of the VVs.

Table 1

Clinical data, surgical time, amount of bleeding, number of incisions, and in-hospital time for the two groups (means \pm SD).

	Sex Ratio (M/F)	Age (Years)	Surgical Time (min)	Amount of bleeding (mL)	Number of Incisions	In-hospital Time (days)
Group A	14/18	55 ± 12	56 ± 11	11.6 ± 4.4	3 ± 0.7	6 ± 0.9
Group B	15/17	58 ± 11	90 ± 33	24.7 ± 6.6	6.3 ± 2.4	6.8 ± 1
t value		$t = 1.163$	$t = 5.472$	$t = 9.298$	$t = 7.674$	$t = 3.11$
p value		$p = 0.25$	$p < 0.05$	$p < 0.05$	$p < 0.05$	$p < 0.05$

Group A, Trivex system group; Group B, Point-form-stripping combined with foam sclerotherapy group.

To prevent inflammation, it was essential to remove all tumescent fluid after the operation by extrusion, leaving an incision so small that no suture is needed.

Point-form-stripping combined with foam sclerotherapy (FS) group

In this group, patients underwent GSV trunk high ligation and EVLA or stripping, and point-form-stripping combined with FS for the branches. A sclerosing agent of 3% polidocanol was used, and the process of sclerosing foam following the Tessari method⁹ was initiated with two 5 mL injection syringes and a three-way stop-cock. Sclerosing foam was prepared with a double-syringe technique, the ratio of sclerosant to air was 1:4 with one syringe filled with 1 mL of 3% polidocanol and the other syringe filled with 4 mL air, the air and liquid polidocanol were mixed by pushing the two syringes back and forth at least 20 times to form a uniform and delicate foam. Before the operation, patients were required to stand for a while to allow bulging of the VVs, and to have them marked. After the trunk was finished, a tourniquet was used in the thigh to engorge below the marked branch of varicosity and about 3–5 mL of sclerosing foam was injected via several acupuncture at each site; after the injection, the compression was performed to make sure all of the VVs filled with the sclerosing foam. The next step is the point-form-stripping where severe varicosities was removed through small 2–3 mm incisions in the skin overlying the VVs which were separated from the superficial fascia and pulled out as much as possible; to prevent bleeding, ligation of the venous stump or hemostasis by compression was performed.

Statistical analysis

Statistical analyses were performed by using predictive analytics software (PASW Statistics version 18.0, IBM Corp., Armonk, NY USA). Numerical data were expressed as means \pm standard deviation and were compared using independent *t*-tests. Qualitative data were expressed as frequency or percentage and were compared using χ^2 tests. The level of significance was set at $p < 0.05$.

Results

Detailed clinical characteristics of the patients are shown in Table 1. There were no significant differences with respect to satisfaction score, improvement in clinical symptoms, recurrence, or SSI between the groups ($p > 0.05$) (Table 2). The surgical time in Trivex system group was significantly shorter than for the point-form-stripping combined with FS

Table 2

Outcomes in the two groups.

	SSI	Pain/Phlebitis	Recurrence	Improvement in Clinical Symptoms	Satisfaction Score
Group A	0/32	5/32	0/32	2/32	3/32
Group B	0/32	17/32	0/32	4/32	5/32
t value		$\chi^2 = 9.974$		$t = 0.736$	$t = 0.571$
p value		$p < 0.05$		$p > 0.05$	$p > 0.05$

Group A, Trivex system group; Group B, Point-form-stripping combined with foam sclerotherapy group; SSI, surgical site infection.

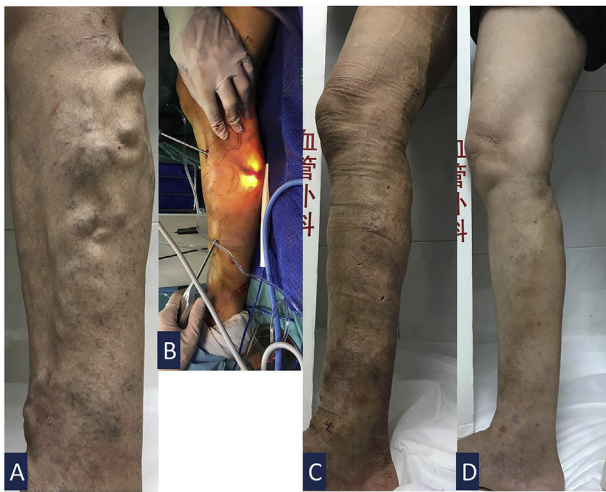


Fig. 1. Clinical symptoms of the lower extremity in a patient of the Trivex system group.

A. preoperative; B. intraoperative; C. two days postoperative; D. two months postoperative.



Fig. 2. Clinical symptoms of lower extremity in a patient of the point-form-stripping combined with FS group.

A. preoperative; B. one month postoperative.

group ($p < 0.05$). The mean operative time for the Trivex system group (Group A) and the point-form-stripping combined with plus FS group (Group B) was 56 ± 11 min and 90 ± 33 min, respectively. Similarly, significant differences with respect to the amount of bleeding volume, in-hospital time, and number of incisions were observed in the Trivex system group as compared to the point-form-stripping combined with FS group ($p < 0.05$) (Table 1).

The anticoagulant enoxaparin (0.4 mL) was routinely injected subcutaneously 6 h postoperatively; there were no DVTs, recurrence of varicosity, or SSIs that occurred during the 45 months of follow-up.

Postoperatively, symptoms of discomfort or other lower limbs signs (such as hyperpigmentation or pain) were greatly improved for patients in both groups (Figs. 1 and 2).

Discussion

GSV vein varicosities have been reported to have a high incidence and the CEAP classification is used to describe the degree of VVs with the “C” part of the CEAP classification being the clinical evaluation, from C0 to

C6. Therapy for VVs is multimodal and depends on the individual clinical findings. In our study, all cases belonged to grades C2–C5 and their typical characteristics are that large branches gather into a cluster which we call primary severe superficial VVs of the lower extremity. They are the most likely to form superficial thrombophlebitis or a rupture hemorrhage if not treated. Point-form-stripping was widely adopted in the clinical practice prior to the invention of the Trivex system, but point-form-stripping remains very much in use today, not only reducing operative time compared to conventional surgical approaches but also involving lesser pain, lesser hemorrhage volume, and faster recovery, with fewer incisions; all very important factors for young patients in particular. In addition to the two options mentioned above for big branches, ultrasound-guided foam sclerotherapy (UGFS) could be another possible option for the therapy of VVs. Although there is no need to use an anesthetic and UGFS can be performed in a treatment room with the patient able to go back to work after the procedures, there is the possibility of complications including bruising, skin pigmentation, and thrombophlebitis, and the effectiveness of UGFS is uncertain. Randomized controlled trials are required with long-term follow-up to establish the effectiveness of UGFS.¹⁰ In our study, one patient underwent surgery on both lower extremities where bilateral GSVs were treated with high ligation combined with EVLA. The venous branches were treated with point-form-stripping and the Trivex system. Postoperatively, both legs felt very cold though the lower extremity arteries were normal. We speculate that skin paresthesia is associated with EVLA for the trunk of the GSV in the lower two-thirds of the calf because it closely parallels with the saphenous nerve, and we believe that it had nothing to do with the Trivex system. The incidence of this symptom is not high.¹¹

We noticed that the amount of tumescent local anesthesia should be well controlled in the procedure and that it must be expelled from the subcutaneous tissue completely or it cause inflammation and swelling. If necessary, more holes can be stabbed in the area by a surgical knife blade; there is no need to sew the incisions closed. With proper training and experience, utilization of the Trivex system with a lower oscillation frequency and secondary tumescence results in a good outcome and high patient satisfaction. A review of 547 cases performed by one surgeon over a 9-year period is beneficial in analyzing the outcomes and complications associated with the Trivex system approach.¹²

Conclusions

The Trivex system for the treatment of primary severe superficial VVs of the lower extremity is associated with fewer incisions and faster recovery, with patients suffering less operation time and shorter in-hospital stays. Midterm follow-up results show that there is no obvious relapse or complications and that the quality of life significantly improved with symptoms disappearing after the procedure. Patients should be strictly selected as primary severe superficial VVs of the lower extremity could benefit more than other types of superficial VVs of the lower extremity. Clinicians should do more training exercises to enhance their operative skills for fewer complications and better effect. Perhaps because of its complex installation process, large database and long-term follow-up studies are rarely reported, meaning that prospective randomized studies are needed to prove the effectiveness of the Trivex system.

Declaration of competing interest

None.

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