Research Column

Review of article: Xin Li, Bo Yang, Xianlun Li, Shiyan Ren. Prospective comparison of effect of ligation and foam sclerotherapy with foam sclerotherapy alone for varicose veins. *Ann Vasc Surg* 2018;49:75-79

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Varicose veins are dilated, often palpable subcutaneous veins with reversed blood flow, most commonly found in the legs. The Society for Vascular Surgery and the American Venous Forum recommend using the CEAP classification system to document the clinical class (C), etiology (E), anatomy (A), and pathophysiology (P) of chronic venous disease.[1] The clinical component consists of C0 through C7; varicose veins are classified as C2.[1] Varicose veins of the lower limbs are dilated subcutaneous veins that are ≥3 mm in diameter measured in the upright position.[1] Varicose veins may become more severe over time and can lead to complications such as changes in skin pigmentation, eczema, superficial thrombophlebitis, bleeding, loss of subcutaneous tissue, and venous ulceration.[1,2] Treatment options for varicose veins include sclerotherapy, foam sclerotherapy of large veins, laser surgeries, high ligation with vein stripping, and endoscopic vein surgery.

The purpose of this clinical trial was to compare the effects of ligation after foam sclerotherapy (FSL) versus foam sclerotherapy (FS) alone in the treatment of varicose veins. The investigators hypothesized that the effect of ligation of the ablated varicose veins after the FSL is not inferior to that after FS alone in ablating the varicose vein.

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METHODS

This was a prospective, randomized, clinical trial of 182 patients conducted over a 5-year period from January 2011 to July 2016 in China. Patients with varicose veins were randomly assigned to either FSL or FS alone. To achieve randomization, patients were asked to blindly select a sealed envelope to determine the treatment group assignment. Patients were aged 18–80 years, with varicose veins classified as C2-C4 according to the CEAP classification system. Patients with severe peripheral artery disease, active thrombophlebitis, known patent foramen ovale, family history of deep vein thrombosis, known thrombophilia or coagulation disorders, and postthrombotic syndrome and who are pregnant were excluded. Patients gave informed consent and agreed to attend the follow-up appointments.

Demographic information and medical history were obtained. All the patients had great saphenous vein insufficiency and large superficial varicosities. Photographs of the affected leg area were taken before treatment and at each follow-up visit. Ultrasound images of the affected leg were obtained before and at 6 months after treatment. FSL was performed under local anesthesia. Ligation after FS was performed in an effort to prevent reflux of blood to the ablated veins, allow for good closure of treated veins, and minimize the risk of superficial venous thrombosis. No pain medications or antibiotics were administered on the day of treatment. Compression stockings were applied immediately after the procedure. Patients were encouraged to walk and were discharged home. CEAP scores were compared before treatment and at 6 months after treatment. Patients were followed up at 2 weeks, 4 weeks, and 6 months.

RESULTS

Of the 182 patients, 94 (52%) were treated with FS alone and 88 (48%) were treated with FSL. The two groups were similar in

demographics, CEAP classifications, and proportion of pain or discomfort. Patients treated with FS alone versus those treated with FSL had a higher incidence of phlebitis (development of a thread vein) within 4 weeks (14.9% vs 1.1%, $P = .002$) and at 6 months (10.6% vs 0, $P = .002$); a higher incidence of tenderness/discomfort at 6 months (9.8% vs 0, $P = .003$); and a higher recanalization rate (8.5% vs 1.1%, $P = .007$) at 6 months. Other reported complications within 4 weeks and at 6 months were numbness, bruising, skin pigmentation changes, and lumpiness. These complications, however, were not significantly different between groups. CEAP scores at 6 months after treatment decreased to C0 in both the groups.

LIMITATIONS

A limitation of the study identified by the investigators was the short duration of follow-up after treatment. In addition, the authors acknowledged the limited number of patients in the study.

CONCLUSION

The investigators concluded that this prospective randomized clinical trial produced evidence that FSL is a more effective treatment option than FS alone in management of patients with varicose veins. The main benefit to the patients was a lower incidence of phlebitis and tenderness/discomfort in the FSL group. There was also a lower recanalization rate in the FSL group.

IMPLICATIONS FOR PRACTICE

Although this study was conducted in China, findings are relevant and applicable to other countries. Approximately 23% of American adults have varicose veins.[1] Varicose veins are more commonly seen in women and in individuals aged 50 years and older.[1,2] Varicose veins can predispose to more advanced chronic venous diseases, including skin changes and healed or active venous ulcers.[1] These advanced stages not only affect the patient physically but psychosocially as well.

Future studies with FS with or without ligation compared with other established treatment modalities for varicose veins such as endovenous laser and radiofrequency ablation therapies would be useful. These comparisons may provide support for the most efficacious treatment with the least complications and best outcomes. In addition, assessments of the venous status beyond 6 months will provide more data on long-term outcomes. An extended follow-up period is necessary to fully observe the durability of the treatment. A larger sample is similarly important. The use of standardized assessment tools to determine the quality of life in patients after treatment would provide valuable information.

Vascular practitioners should be familiar with the medical history, clinical examination, and diagnosis of varicose veins. Knowledge on using appropriate diagnostic tools, vascular laboratory studies, and CEAP classification system is essential. Recommended treatment options should be based on the most current evidence-based clinical practice guidelines. Vascular practitioners should provide patients with thorough information to make appropriate and informed treatment decisions.

REFERENCES

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