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Original Research

Feasibility and safety of foam sclerotherapy followed by a multiple subcutaneously interrupt ligation under local anaesthesia for outpatients with varicose veins

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HIGHLIGHTS

- A multiple interrupt ligation after foam sclerotherapy for varicose veins (FSL) is feasible and effective.
- This FSL procedure can be performed as a day surgery.
- The FSL may warrant a good closure of treated varicose veins and can minimize the risk of superficial venous thrombosis.

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ABSTRACT

Purpose: To prospectively evaluate the feasibility and safety of foam sclerotherapy and ligation (FSL) for outpatients with varicose veins under local anaesthesia.
Methods: 136 outpatients with varicose veins who were unwilling to be hospitalized underwent FSL. FSL is a technique in which the dilated varicose veins were ligated subcutaneously after foam sclerotherapy with an absorbable suture. Patients were reviewed at 1, 3, 6 and 12 months after FSL. Pain scores were recorded after FSL. The revised venous clinical severity scorer (rVCSS) and clinical, etiological, anatomical, and pathological classification (CEAP) were used to evaluate the improvement at 3 months after treatment.
Results: 146 limbs in 136 outpatients with varicose veins were managed with FSL. The pain scores decreased following FSL, CEAP classification score, the rVCSS values improved 3 months post-intervention. No significant postoperative complications were observed on follow-up.
Conclusion: FSL is feasible, safe and easily to perform under local anaesthesia for outpatients with varicose veins.

1. Introduction

Varicosities are common conditions, the incidence of varicose veins is reported 10%–40% [1–4]. The treatment options for the varicosities include traditional ligation and stripping, endovenous laser ablation, radiofrequency ablation, and foam sclerotherapy [3,5–10]. Ambulatory phlebectomy is mostly used for superficial varicosities; however, it has many postoperative complications such as recurrence, deep veins thrombosis, and nerve injuries. In recent decade, foam sclerotherapy (FS) has become increasingly popular for the treatment of varicose veins [2–5,8,10]. However, the main drawback of FS is that it cannot be used for large varicose veins due to recurrence of varicosities. Incomplete closure of treated veins and or subsequent recanalization are critical reasons

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of recurrence [4,8]. We hypothesize that ligation of the varicose veins treated by FS may prevent from the recurrence, as it further strengthens the effect of FS and minimizes the risk of recanalization of the treated varicose veins. The aim of the present study was to assess the feasibility and safety of FSL for outpatients with varicose veins.

2. Materials and methods

Between September 2010 and December 2015, 136 consecutive outpatients with varicose veins were prospectively evaluated and treated. Inclusion conditions were outpatients with varicose veins C2 to C4 who refused to have phlebectomies because they were unwilling to be hospitalized, outpatients with saphenofemoral junction incompetence confirmed with an ultrasonography, patients who were willing to provide a written consent for outpatient treatment and to come for follow-up regularly. Exclusion criteria included outpatients with varicose veins C1, C5,C6, any inpatients with varicose veins, patients who refused to provide a written consent for treatment or unwilling to come for follow-up, patients with severe peripheral arterial disease, active thrombophlebitis, pregnancy, known patent foramen ovale, and post-thrombotic syndrome.

All patients provided an informed, written consent for FSL procedure. The clinical work was conducted in accordance with the Helsinki declaration and was approved by the institutional review board. Patients' demographic information, ultrasound examination, and medical histories were documented.

The severity of varicosities were studied using the clinical, aetiological, anatomical, and pathological classification (CEAP), and clinical severity was graded using the revised venous clinical severity score (rVCSS) and SF-36. The physical examination and ultrasonography were performed blindingly for lower extremities before and after FSL. The length and maximum diameter of varicose veins was measured in all patients. An investigator who was responsible for CEAP, rVCSS and SF-36 study and those who perform the ultrasonography for patients were blinded to the objective of this study.

2.1. FSL procedure

FSL was performed under local anesthesia on one side of lower limbs in case of varicosities on both lower limbs. Polidocanol (Aethoxysklerol 2%, Tianyu Pharm., Xian, China) was used to generate sclerosing foam by a modified Tessari technique (polidocanol/air ratio = 1/4). A total of 4–8 ml of 2% polidocanol was used to generate sclerosing foam for SF. The varicose veins treated by SF were ligated subcutaneously with 3–0 absorbable (coated Vicryl plus, VCR442.P30, Ethicon, Inc) with a distance of 4 cm between two ligations. Medical compression stockings were put on immediately after FSL for 15 days to prevent blood reflux into the treated veins thereby ensuring a secure closure of varicose veins. All patients did not stay in hospital and went home immediately after FSL. No antibiotics or infusion were provided. Technical success in FSL was defined as successful access, delivery of foam during procedure, and disappearance of varicose veins at 3-month follow-up.

2.2. Follow-up

Patients were followed up 15, 30 days, 3, 6, 12 months after treatment. The 'C' of the CEAP and the rVCSS score were evaluated at 3-month follow-up. Patients were assessed by comparing the "C" of the CEAP score and the rVCSS score, SF-36 at 3-month in comparison with baseline blindingly. Doppler examination was performed on follow-up. Any adverse effects, including neurological effects, recurrence, hyperpigmentation, allergic reaction, deep-vein thrombosis, or paresthesia were routinely documented. The investigators who were responsible for CEAP, rVCSS scores and ultrasound study were blinded to the objective of this study.

2.3. Statistical analysis

Quantitative data were analyzed for normal distribution with the method of Kolmogorov-Smirnov-Lilliefors. Differences between groups were analyzed by a Student-t-test or Mann-Whitney-Wilcoxon test based on their distribution. Mean and SD was used to express the normal distributed data. Median (inter-quartile range, IQR) was used for non-normal distributed data. The statistical analysis indicated the distributions of "C" of the CEAP score, the rVCSS score and SF-36 data are non-normal. Categorical data were analyzed by a Chi-squared test. A probability of less than 0.05 was considered as statistically significant. Statistical analysis was performed using software SPSS 13.0.

3. Results

A total of 136 patients (62 males, 45.6%; mean age 47 years) were treated with FSL successfully. All patients had GSV insufficiency and superficial varicosities. The mean diameter of the varicose veins in supine position was 8.1 mm (range 5.0–12.4 mm) before treatment. Disappearance of the varicosities was documented in all limbs at 3-month follow-up. The ultrasonographic studies showed that no visible blood flow and no compressibility along entire course of the treated varicose veins at 3, 6 and 12 months after FSL.

All patients were symptomatic with CEAP class 2 to 4 (median 2) prior to FSL. On follow-up at 6-month, CEAP scores decreased to values of 0–1 (median 0) ($P < 0.001$). The rVCSS values ranged from 2 to 11 (median 7) on baseline and decreased to 0–3 (median 2) after FSL ($P < 0.001$). The values of AVVQ and SF-36 were decreased significantly at 3- month after FSL in comparison with baseline ($P < 0.001$) (Table 1). The pain scores were 2–4 during first 24 h after FSL, decreased to 1–2 on day 2 and disappeared on day 3 after FSL.

Table 1
Clinical assessment of the patients before and 6 months after treatment.

Total patients (n = 136)	Pretreatment	6-month after treatment	p
CEAP "C" scores	2(2,4)	0(0,1)	<0.001
rVCSS scores	7(7,8)	2(2,3)	<0.001
AVVQ	19(18,19)	11(10,12)	<0.001
SF-36 physical component	49(48,50)	56(56,58)	<0.001

CEAP, clinical, aetiological, anatomical, and pathological classification.
rVCSS, revised venous clinical severity score.

Table 2
Complications according to the Clavien-Dindo classification system.

Complications	Total N = 16(%)
Grade I	16(100)
Cough	1
Thrombophlebitis	1
Paresthesia	1
Sclerosing node	5
Cord-like tightening	4
Pain killer	4
Grade II	0
Grade III	0
Grade IV	0
Grade V	0