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ORIGINAL RESEARCH

Effect of Transluminal Injection of Foam Sclerotherapy Combined with Endovenous Thermal Ablation of Varicose Veins

Satoshi Watanabe [*], **Soji Nishio, Takafumi Tsuji, Shinya Fujita, Eisho Kyo**

Department of Cardiology, Kusatsu Heart Center, Japan

Objective: The combination of endovenous therapies with stab avulsion or ultrasound guided foam sclerotherapy is widely performed. However, these conventional techniques tend to result in incomplete avulsions or persistent varicosities.

Methods: One hundred and thirteen legs in 97 consecutive patients who underwent 1470 nm laser ablation for great saphenous varicose veins were enrolled. The foam sclerosing agent was injected via the sheath after endovenous laser ablation (EVLA). Patients were divided into two groups: EVLA only group (Control; $n = 50$) and EVLA and transluminal injection of foam sclerotherapy (TLFS) group (SCL; $n = 63$).

Results: At three month follow up, reflux was abolished throughout all treated great saphenous veins (GSVs) when assessed with Duplex ultrasound. Thrombophlebitis was observed in two patients in the SCL group ($p = .13$). Additional second stage sclerotherapy was needed in the Control group ($n = 33$, 66%) *vs.* SCL group ($n = 2$, 3%; $p < .0001$). The venous clinical severity score (VCSS) was significantly improved in the SCL group (changes of VCSS, Control -3.3 ± 1.7 and SCL -4.4 $\pm$ 1.0; $p < .0001$). Univariable and multivariable analyses revealed that, among age, sex, Clinical-Etiology-Anatomy-Pathophysiology classification, linear endovenous energy density, and TLFS, TLFS was the only significant factor of improved VCSS (hazard ratio $= -0.96$; 95% confidence interval $= -1.4$ to -0.58; $p < .0001$).

Conclusions: TLFS combined with EVLA may be an easy, safe, and effective procedure with acceptable complications *vs.* EVLA alone and reduces additional second stage interventions.

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INTRODUCTION

Endovenous varicose vein therapies are now the preferred treatment option *vs.* traditional surgical procedures and are currently considered as the first choice. Stab avulsion (SA) or ultrasound guided foam sclerotherapy (UFS) combined with endovenous laser ablation (EVLA) also is performed widely. However, these conventional techniques tend to result in incomplete avulsions or persistent varicosities regardless of the amount of effort or time put into the procedure. Previously reported extended EVLA of great saphenous vein (GSV) and above knee EVLA with below knee foam sclerotherapy via the endovenous catheter is safe and effective.[1] In this study, an endovenous catheter was inserted via a sheath; and thus it could be considered whether a transluminal injection of foam sclerotherapy (TLFS) via this sheath might cover the whole varicose vein *vs.* local SA/UFS. The aim of this study was to assess the short term efficacy, patient satisfaction, and effects on venous clinical severity score (VCSS) of TLFS in the treatment of GSV varicose veins.

METHODS

Patients

From March 2017 to March 2019, 99 consecutive patients with 113 legs were enrolled in the study. Eligible patients had a diagnosis of unilateral/bilateral GSV varicose veins, with clinical class C_2–C_6 disease according to the Clinical-Etiology-Anatomy-Pathophysiology classification. Great saphenous insufficiency was defined as reflux >0.5 s using colour duplex ultrasound along with the Valsalva method or the lower extremity milking method. The indication for EVLA was a symptomatic primary varicose vein. Exclusion criteria were (1) recurrent varicose veins following previous surgery, EVLA, or UFS; (2) sclerosant hypersensitivity; (3) serious systemic diseases, such as deep vein thrombosis (DVT) and chronic obstructive pulmonary disease; (4) serious lower limb ischaemic disease (lower extremity

* Corresponding author. Department of Cardiology, Kusatsu Heart Centre, Komaizawa-cho 407-1, Kusatsu, Shiga, Japan.

E-mail address: watanabe@kusatsu-heartcentre.co.jp (Satoshi Watanabe).

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arteriosclerosis obliterans, thromboangiitis obliterans, acute arterial embolism, Raynaud's syndrome); (5) coagulation disorder; and (6) simultaneous EVLA for both great and small saphenous veins. Patients were divided into a conventional EVLA only group (Control; $n = 50$; March—November 2017) and a combined TLFS group (SCL; $n = 63$; December 2017—March 2019). This study was approved by the Ethics Committee. All patients provided written informed consent.

Procedure

The GSV at the lower end of reflux or upper third of the calf was punctured under 1% lidocaine local anaesthesia and under ultrasound guidance. A 6 Fr 15/25 cm introducer sheath (Radifocus™ Introducer II H; Terumo Co., Ltd., Tokyo, Japan) was inserted. Finally, through the introducer sheath, a laser catheter using a 1470nm diode laser [(LEONALD1470; Biolitec, Bonn, Germany) with a radial 2ring fibre ELVeS Radial 2ring™ fibre; Biolitec] was inserted. EVLA was performed from a point just distal to the saphenofemoral junction under tumescent local anaesthesia (0.9% saline 500 mL, 2% lidocaine 30 mL, 0.1% adrenaline 1 mL, 7% sodium bicarbonate 20 mL). The laser fibre was pulled back at 2 mm/s with 8W.

TLFS

Sclerosing foam was prepared using the previously described Tessari method.[2] EVLA was temporarily stopped 2—4 cm proximal to the targeted tributary vein (TV). The tip of the introducer sheath was placed 1—2 cm proximal to the targeted TV. Then, sclerosing foam was injected via the side port while compressing the GSV above the targeted TV (Fig. 1A). After injecting the sclerosant, EVLA was restarted. Ultrasound was used to check that the sclerosant was in the targeted TV. If needed, sclerosing foam was injected into the next target by a similar method (Fig. 1B). When the targeted TV was located below the insertion site, sclerosing foam was injected just before removing the sheath. The maximum dose was 2 mL of 1% polidocanol with 4—6 mL air. After the procedure, patients were encouraged to wear compression stockings during the first 24 hours and advised to continue wearing them for one month but only during the daytime.

Assessment of outcome

Before the procedure, VCSS were recorded. A post-interventional check up took place one day, one month, and three months after the procedure. Patients were asked about their recovery status and complications. Also, persistent varicosities, DVT, and endovenous heat induced thrombosis were checked for visually and by ultrasound. Finally, after three months, VCSS were recorded.

Statistical analysis

Continuous variables were presented as mean ± standard deviation. Categorical variables were presented as numbers (percentages). Student's *t*-test was used to test for between group differences in independent continuous parametric and non-parametric variables. Chi-square test was used to test for differences between categorical variables. Logistic regression analysis was conducted to identify the predictors of improved VCSS. Candidate predictors were selected based on clinical importance and special interests associated with EVLA.

RESULTS

There were no significant differences between the groups in the baseline patient characteristics (Table 1). EVLA was technically successful in all cases. No major complications were observed during follow up. Thrombophlebitis was observed in two patients in the SCL group ($p = .13$). Additional second stage sclerotherapy was required significantly more often in the Control group ($n = 33$, 66%) than the SCL group ($n = 2$, 3%; $p < .0001$).

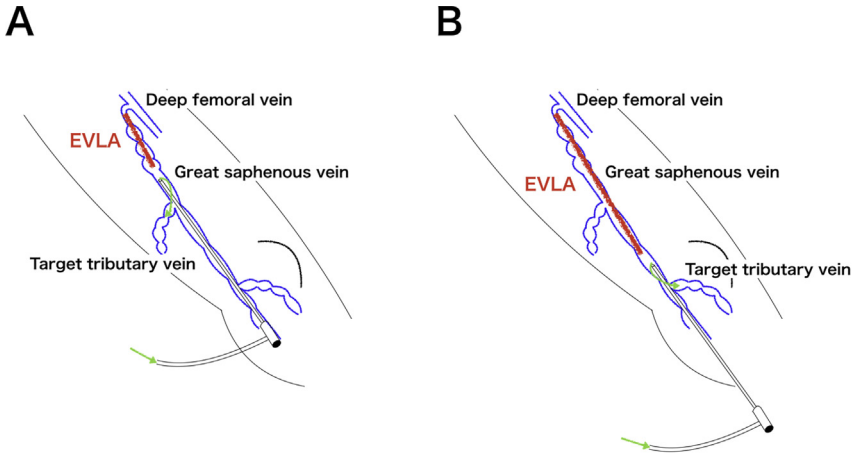

Figure 1. (A) EVLA temporarily stopped at 2—4 cm proximal to targeted TV (red line; EVLA site). Simultaneously, the tip of the sheath was placed 1—2 cm proximal to targeted TV. Then, sclerosing foam was injected via the side port (green arrow). (B) Sclerosing foam was injected into the next target by a similar method.

Table 1. Results.

Variable, *n* (%)	Control *n*=50 (44%)	SCL *n*=63 (56%)	*p* value
Age, years	66±12	67±12	.64
Gender (female)	34 (68%)	40 (63%)	.62
CEAP classification			
C_2	10 (20%)	7 (11%)	
C_3	2 (4%)	4 (6%)	
C_{4a}	26 (52%)	41 (65%)	
C_{4b}	6 (12%)	6 (10%)	
C_5	4 (8%)	5 (8%)	
C_6	2 (4%)	0 (0%)	
All patients: Etiologic classification, Primary (Ep); Anatomic classification, Superficial (As); Pathophisiologic classification, Reflux (Pr)			
EVLA procedure			
Target GSV (left/right)	21/29	31/32	
Target GSV diameter, mm	7.9±1.9	8.0±1.2	.76
Procedure success	50 (100%)	63 (100%)	
Ablation length, cm	42±9	41±7	.59
Total laser energy, J	1322±522	1276±316	.57
LEED, J/cm	31±12	31±5	.79
Major complications	0 (0%)	0 (0%)	
Thrombophlebitis	0 (0%)	2 (3%)	.12
Additional sclerotherapy	33 (66%)	2 (3%)	<.0001
Assessment of VCSS			
Pre-procedure VCSS	10.4±2.7	11.2±2.3	.07
Post-procedure VCSS	7.1±3.5	6.8±2.5	.63
Changes in VCSS (Post-Pre value)	−3.3±1.7	−4.4±1.0	<.0001

Data are presented as mean ± standard deviation (SD) or number of patients (%). CEAP = Clinical-Etiology-Anatomy-Pathophysiology; EVLA = endovenous laser ablation; GSV = great saphenous vein; LEED = linear endovenous energy density; VCSS = venous clinical severity score.

There was no significant difference in the pre-procedure VCSS between the groups (10.4 ± 2.7 *vs.* 11.2 ± 2.3, $p = .07$). Changes in VCSS (post-pre values) were significantly larger in the SCL group *vs.* the Control group (−3.3 ± 1.7 *vs.* −4.4 ± 1.0, $p < .0001$) (Table 1).

Univariable ($p < .0001$) and multivariable [HR = −0.96 (95% CI; −1.4 − −0.58), $p < .0001$] analyses revealed that TLFS was the only significant factor for improved VCSS (Table 2).

Table 2. Univariable and multivariable predictors affecting the changes of VCSS.

Variable	Univariate *p* value	Multivariate HR (95% CI)	*p* value
Age	.36	NA	
Gender (female)	.33	NA	
CEAP classification	.25	NA	
TLFS	<.0001	−0.96 (−1.4 to −0.58)	<.0001
LEED	.16	NA	

CEAP = Clinical-Etiology-Anatomy-Pathophysiology; CI = confidence interval; HR = hazard ratio; LEED = linear endovenous energy density; TLFS = transluminal injection of foam sclerotherapy; VCSS = venous clinical severity score.

DISCUSSION

It remains undefined whether EVLA alone is better than EVLA+SA/UFS. A previous study reported that combined EVLA plus phlebectomy improved clinical outcomes and reduced the need for further procedures.[3] On the other hand, several investigators have also claimed that concomitant phlebectomy could be omitted because EVLA improved the symptoms.[4] Because of the use of conventional hooks, only superficial varicose veins near the incision site could be avulsed. Numerous additional incisions would be needed to remove all the varicosities. The number of stab wounds tends to increase once the vein is torn and retracts under the skin, as it becomes difficult to re-grasp and a new incision is often required. There are some complications that are directly related to SA, such as bleeding, nerve damage, and infection. Therefore, many patients could avoid unnecessary scars, extra pain as a result of phlebectomy, and complications by undergoing TLFS. If phlebectomy is still needed after TLFS, this often allows for a smaller second stage procedure.

UFS+EVLA is also widely performed and is less invasive and more acceptable not only to patients but also to the operator. Wang et al. demonstrated that simultaneous tributary UFS with truncal EVLA is a promising, feasible, and safe treatment approach *vs.* tributary EVLA with truncal EVLA.[5] Theivacumar et al. showed that EVLA down as far as the lowest point of GSV reflux also resulted in shrinkage of the majority of varicose veins, making delayed sclerotherapy unnecessary.[1] However, previous clinical studies have not fully reviewed TLFS. For TLFS, an adequate length of sheath must be selected according to the location of the targeted TV.[6] In the present study, ultrasound checks were made to see whether the sclerosant stayed in the vein. The method was based on the goal that the sclerosant should fill into the distal end of the targeted vein. Interestingly, there were few complications related to foam sclerotherapy. Thrombophlebitis was observed in only two patients, as the total sclerosant volume was relatively small.

This study has several limitations: it was (1) prospective but not randomised and controlled, (2) limited by its single centre design and relatively small number of patients, and (3) long term follow up is needed for further studies.

TLFS+EVLA may be an easy, safe, and effective procedure, with acceptable complications *vs.* EVLA alone and may also reduce additional second stage interventions.

CONFLICT OF INTEREST

None.

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