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Abstract Title: Are the Vein Diameter and the Treatment Distance Related to Postoperative Obstruction?

ABSTRACT PREVIEW: ARE THE VEIN DIAMETER AND THE TREATMENT DISTANCE RELATED TO POSTOPERATIVE OBSTRUCTION?

Are the vein diameter and the treatment distance related to postoperative obstruction?

Takahiro Imai

Department of Vascular Surgery, Nishinokyo Hospital, Nara, Japan

Introduction: Physician-led clinical research was conducted to observe efficacy and safety of cyanoacrylate closure (CAC) using VenaSeal™ at 12 centers in Japan.

The study was conducted as a multicenter collaborative study (12 institutions) by experienced physicians and well-equipped medical institutions regarding treatment of varicose veins, targeting 120 cases, and prospectively conducted according to the procedure.

Objective: Most of the studies on postoperative closure rate of targeted veins treated with CAC using NBCA have reported results of GSV alone or without distinguishing between GSV and SSV, and there are few reports on the results of SSV alone. Therefore, it has been said that it is important to evaluate the postoperative closure rate of SSV alone in order to establish high-quality evidence.

Methods: We included 143 legs of 125 patients who underwent CAC with VenaSeal™ at 12 centers in Japan from December 2019 to June 2020 for the diagnosis of primary varicose veins. Ages ranged from 39 to 88 years, and gender distribution was 39 males and 86 females. The targeted vessels were 72 GSV and 71 SSV. The observation period was one year, and the intervals were at preoperative, immediate postoperative, 7 POD, 30 POD, 90 POD, and one year postoperative. The study point was closure rate of SSV and evaluated by postoperative ultrasonography, and occlusion was defined as the closure of the target vein segment and the absence of an opening more than 5 cm from the starting point of treatment. The cutoff point of preoperative maximum diameter for postoperative occlusion in the SSV group was analyzed using the ROC curve to determine whether successful or unsuccessful occlusion can be effectively discriminated at 1 year using the maximum diameter of the vein as the test variable.

Results: In this research, the postoperative closure rate of the target vein was 95.0% for GSV and 90.2% for SSV, and Fisher's exact test was used to compare the 1-year closure rate between the two groups, GSV and SSV. The significance probability was calculated with exact significance probability, and the test was two-tailed, indicating that there was no difference in the 1-year postoperative closure rate between the GSV and SSV groups ($P=0.491$). The ROC curve was validated by the area under the curve (AUC) and the probability of significance, and the Youden index was used to determine the optimal cutoff value. The results of ROC analysis showed that $AUC=0.686$ and $P=0.139$, and that the maximum vein diameter could not be used as an index to significantly discriminate whether occlusion was possible. In addition, multiple logistic regression analysis was performed to analyze the factors affecting occlusion, with the treated vein patency (successful/failed occlusion) at 1 year postoperatively as the dependent variable, and the maximum vein diameter and length of treatment as independent variables. Forced entry method was used on the

independent variables to be chosen by simultaneous variable selection for multivariate analysis, and the Wald test was applied to test the regression coefficients to determine the significance of the factors. Multiple logistic regression analysis showed that neither of the two factors, maximum vein diameter nor treatment length, was significant for successful or unsuccessful occlusion ($P > 0.05$).

Conclusion:

We investigated closure rate of CAC using VenaSeal™ for GSV and SSV at 12 centers in Japan during the first year postoperative. Although the closure rate of SSV was lower than that of GSV, good results were obtained throughout the study. According to the author's research, two retrospective studies have been reported thus far, and the studies concluded that the postoperative closure rate of SSV is equal to that of GSV. The confluence of SPJ and SSV is anatomically varied, and in recent years, endovascular treatment such as endovenous ablation is recommended over surgical treatment. Considering this history, CAC seems appropriate for the treatment of SSV.

Categories:

Superficial Venous Intervention – Miscellaneous

References:

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4. Gloviczki P, Lawrence PF, Wasan SM, et al: The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part I. Duplex Scanning and Treatment of Superficial Truncal Reflux: Endorsed by the Society for Vascular Medicine and the International Union of Phlebology. *J Vasc Surg Venous Lymphat Disord* 2022: 1-31

Table 1. Baseline characteristics.

Characteristic	GSV		SSV	
	Mean \pm SD (range) or number (frequency)		Mean \pm SD (range) or number (frequency)	
Age, years	70.3 \pm 10.5 (39-87)		67.6 \pm 11.2 (45-88)	
Gender				
Female	38 (63.3%)		48 (73.8%)	
Male	22 (36.7%)		17 (26.2%)	
Body mass index, kg/m ²	25.2 \pm 3.5 (19.1-32.0)		23.8 \pm 4.1 (17.8-34.4)	
Mean largest diameter, mm	8.3 \pm 2.3 (4.7-13.7)		6.5 \pm 2.4 (2.7-10.6)	
CEAP clinical class				
C2	29 (40.3%)		41 (57.7%)	
C3	29 (40.3%)		18 (25.4%)	
C4a/b	14 (19.4%)		11 (15.5%)	
C6	0 (0.0%)		1 (1.4%)	

GSV: Great saphenous vein; SSV: Small saphenous vein; CEAP: Clinical-etiology-anatomy-pathophysiology.

Table 2. Study eligibility criteria

Inclusion criteria	Patients with symptomatic primary saphenous vein insufficiency diagnosed by clinical symptoms and confirmed by ultrasonography
	Age \geq 40 years and \leq 90 years at the time of screening
	Patients with symptomatic primary saphenous vein insufficiency in one or both legs
	Maximum diameter of the GSV or SSV target vein as measured by duplex ultrasound does not exceed 12 mm
	Patients who do not require Varicectomy
Exclusion criteria	CEAP classification of C6
	Saphenous vein outside the compartment or near the surface of the skin
	MRSA infection
	Previous or suspected deep vein thrombosis or Pulmonary embolism
	Previous or suspected Collagen disease
	Previous or suspected Granuloma
	Daily use of drugs antihistamine (Daily use of antihistamine drugs)
	Multiple allergies
	Known sensitivity to CA adhesives
	Known sensitivity to Formaldehyde
	Allergy to eyelash extensions and nail polish
	Eyelash and nail technicians
	Other patients with contraindications according to national ETA guidelines*

CEAP: Clinical-etiology-anatomy-pathophysiology; MRSA: Methicillin-resistant Staphylococcus aureus, CA: Cyanoacrylate.

Figure 1.

