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The efficacy of endovenously cyanoacrylate adhesive for the treatment of great saphenous vein insufficiency and mid-term follow-up results

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ABSTRACT

Objectives: This study aims to investigate the effectiveness and mid-term results of endovenous administration of n-butyl-2-cyanoacrylate (NBCA) in great saphenous vein (GSV) insufficiency.

Patients and methods: A total of 77 lower extremity GSVs of 65 patients (23 males, 42 females; mean age: 53.7±16.8 years; range, 18 to 89 years) treated endovenously using NBCA between June 2018 and June 2019 were retrospectively analyzed. Clinical examination and color Doppler ultrasonographic examination were performed at 48 h and at 1, 3, 6, and 12 months after the procedure. The Comprehensive Classification System for Chronic Venous Disorders (CEAP) classification, Venous Clinical Severity Score (VCSS), and quality of life scores using the Aberdeen Varicose Vein Questionnaire (AVVQ) were performed before and after the procedure.

Results: Immediately after the procedure and at 48 h of follow-up, the GSV occlusion rate was 100%. The total occlusion rate was 97.4% at 12 months of follow-up. The mean VCSS improved from 5.9±1.5 at baseline to 0.8±0.6 at 12 months (p<001). The mean AVVQ scores improved from 15.4±3.6 at baseline to 3.8±0.7 at 12 months of follow-up (p<001).

Conclusion: Endovenous treatment of GSV insufficiency with cyanoacrylate adhesive is a rapid and effective method and significantly improves the quality of life of patients. In addition, this procedure does not require the use of tumescent anesthesia and compression stockings.

Keywords: Chronic venous insufficiency, n-butyl-2-cyanoacrylate ablation, non-tumescent endovenous ablation, varicose vein.

Chronic venous insufficiency (CVI) and varicose veins occur in approximately one-third of different populations.[1,2] Advanced age, sex, obesity, and family history are important risk factors for CVI.[2-5] Pain, swelling in the leg, fatigue, night cramps, itching, burning, sensitivity, heaviness, restless legs, chronic skin changes and ulcers due to venous dilatation and stasis may accompany CVI. Spontaneous hemorrhage and phlebitis reaction are less frequent findings. The progression of CVI increases symptoms and, thereby, affecting the quality of life considerably.

Surgery (stripping) and endovenous thermal ablation (EVTA) (i.e., radiofrequency and laser ablation) are the primary treatment methods in CVI.[6] The surgical method with stripping in great saphenous vein (GSV) insufficiency requires general or regional anesthesia. However, it has several complications such as hematoma, paresthesia, and recurrence of venous insufficiency.[7] Although radiofrequency and laser ablation are effective treatment methods in CVI, they require compulsory anesthesia to protect the surrounding tissues from thermal injury, which prolongs the procedural time.[8] In addition, as a result of tumescent anesthesia, pain, hematoma, vein wall perforation, skin burns, ecchymosis, skin pigmentation, swelling, and nerve injury may occur.[6,8]

Cyanoacrylate adhesive, which has been recently applied endovenously in the treatment of CVI, does

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not require a tumescent anesthesia and is reported to cause less complications.[9] After its endovenous administration, cyanoacrylate adhesive forms a rapid polymerization reaction and granulomatous foreign body reaction as a result of contact with the blood and vascular tissue. This reaction creates an adhesive effect on the vein wall with an inflammatory effect.[10]

The preliminary results of cyanoacrylate reported in industry sponsored and other clinical studies have demonstrated promising clinical outcomes. However, more data regarding its mid- and long-term results are needed to show the effectiveness of this treatment.[11] Therefore, in the present study, we aimed to investigate the effectiveness and mid-term results of endovenous administration of cyanoacrylate in GSV insufficiency.

PATIENTS AND METHODS

A total of 77 lower limb GSVs of 65 patients (23 males, 42 females; mean age: 53.7±16.8 years; range, 18 to 89 years) whose GSVs were embolized using cyanoacrylate adhesive between June 2018 and June 2019 were included in this retrospective study. Pathological venous reflux was defined as the reverse flow for 0.5 sec in response to release of calf or thigh compression with a patient in standing position and after a Valsalva maneuver in the supine position. A GSV diameter of >5.5 mm and a reflux time with Doppler ultrasonography (USG) of ≥0.5 sec were considered as the primary indication for the procedure. Patients with small saphenous vein and anterior accessory vein failures were excluded from the study. The Comprehensive Classification System for Chronic Venous Disorders (CEAP) classification of the patients was between C2 and C4a before the procedure. Inclusion and exclusion criteria are shown in Figure 1. Patient data were obtained from the electronic hospital database and patient files. A written informed consent was obtained from each patient. The study protocol was approved by the Kafkas University, School of Medicine Ethics Committee (Date: June 25, 2020; No.168). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Family history was reviewed and physical examination, venous Doppler USG examination of both lower extremities, the Venous Clinical Severity Score (VCSS), and quality of life score using the Aberdeen Varicose Vein Questionnaire (AVVQ) before the procedure were recorded. When the patients were called for follow-up appointments, they were questioned in detail to check their suitability for the study. Interventions were performed by a single cardiovascular surgeon with the help of a color

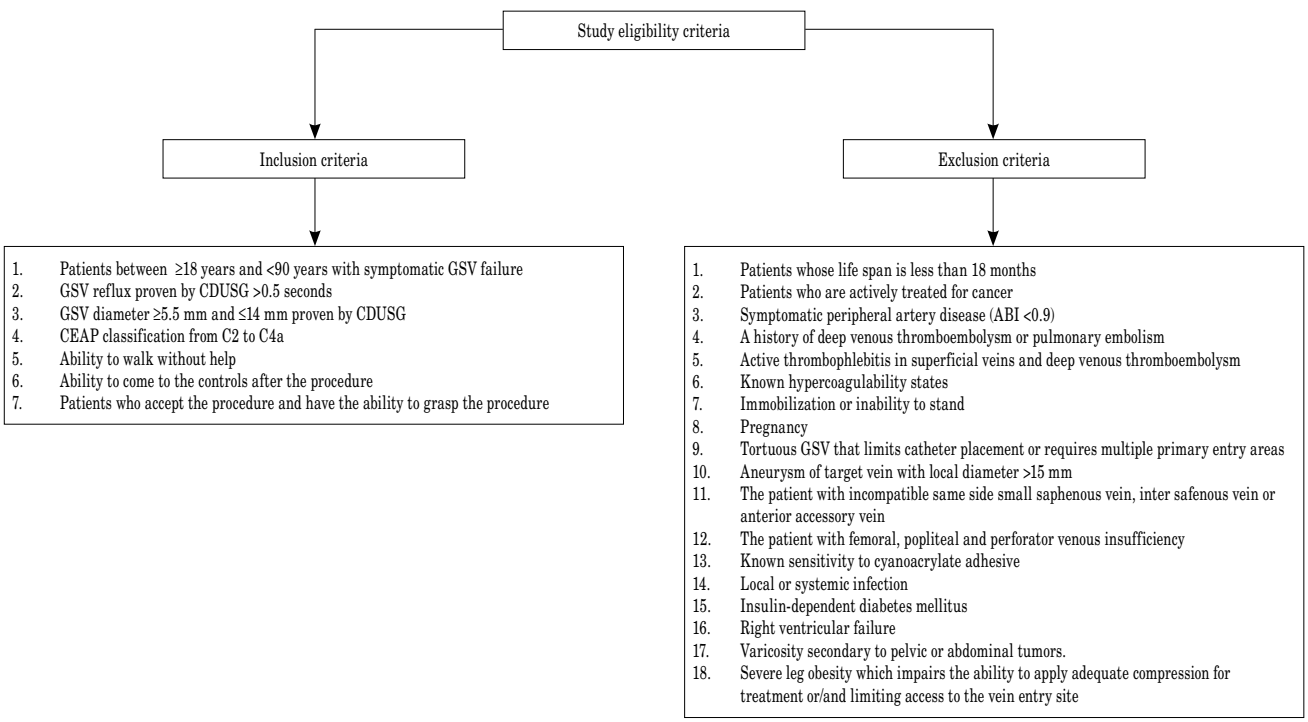

Figure 1. Study flowchart.

GSV: Great saphenous vein; CDUSG: Color Doppler ultrasound; CEAP: Clinical, Etiological, Anatomical, Pathophysiological; ABI: Ankle-brachial index.

Doppler USG. The procedures such as phlebectomy and sclerotherapy were not planned until the third month after the procedure. The duration of the procedure was defined as the time between the entry of cannula into the vein and the time of the removal of the catheter. Procedural success was defined as the complete occlusion of treated vein or <5 cm of partial recanalization. After the procedure, the patients were scheduled for follow-up visit at 48 h and at 1, 3, 6, and 12 months. Medical history, physical examination, and lower extremity color Doppler USG examination were performed during follow-up. The color Doppler USG examination of the treated veins was performed by two radiologists before the procedure and during follow-up. Cardiovascular surgeons obtained the VCSS and CEAP scores. Patients completed the AVVQ before the procedure and during follow-up.

Procedural technique

The content of the n-butyl-2-cyanoacrylate (VenaBlock® Venous Closure System; Invamed, Ankara, Turkey) is shown in Figure 2. All attempts were performed in the operating room under local anesthesia and in sterile conditions. A 6-Fr sheath was percutaneously placed in GSV using the Seldinger technique. Before the procedure, the inside of the VenaBlock® catheter was washed with 5% dextrose to prevent the adhering effect of cyanoacrylate. Subsequently, the catheter behind which a syringe containing 2 mL cyanoacrylate was placed was advanced through an introducer sheath without a long introducer catheter and guidewire. By turning on the light source of the VenaBlock® catheter, the catheter was advanced into the GSV and placed 3 cm distal from the saphenofemoral junction (SFJ) by controlling with color Doppler USG. After positioning the catheter, the operating table is placed in the 30-degree Trendelenburg position to reduce the blood flow. The catheter was filled with cyanoacrylate first by pushing the catheter trigger and, then, it was pushed to deliver the cyanoacrylate into the GSV. Each 10-cm vein segment was completely irrigated with 0.3 mL of cyanoacrylate by pushing the trigger system of the catheter gun for 5 sec and simultaneously by withdrawing the catheter 2 cm per sec, that is, 0.03 mL of cyanoacrylate was given to every 1 cm of vein. This application was repeated for every 10 cm of GSV. Finally, the catheter and the sheath were removed, and manual pressure was applied over the saphenous vein segment treated with cyanoacrylate and on the catheter entry site. Continuous pressure was applied over of the SFJ with the help of color Doppler USG probe, while injecting cyanoacrylate into the vein. The occlusion of GSV was confirmed with the help of color Doppler USG after the procedure. If a non-occluded vein segment was seen, the procedure was repeated for that area. No compression stockings were applied after the procedure according to previous large-scale study results.[12,13] A small adhesive bandage was applied over the puncture site and the patients were discharged on the same day. The patients were instructed to avoid extreme activities for one day and, then, to return to daily living activities.

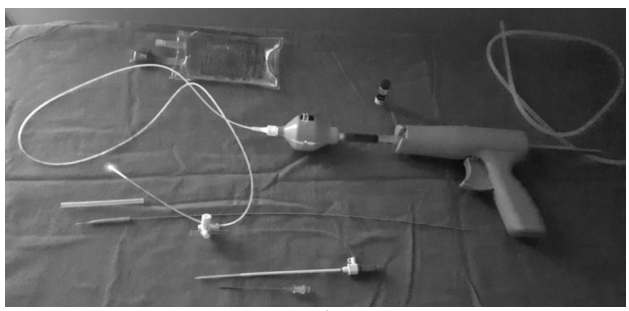

Figure 2. The content of the VenaBlock® Venous Closure System.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 24.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean ± standard deviation (SD) or median (min-max), while categorical variables were expressed in number and percentage. The changes in the VCSS and AVVQ scores were evaluated using the Friedman test. For statistically significant differences, the post-hoc Bonferroni test was used to identify significant pairwise within the group. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients, the main risk factors were family history of venous disease in 16 (24.2%) patients, hypertension in 12 (18.5%) patients, hyperlipidemia in four (6.2%) patients, diabetes mellitus in 10 (15.4%) patients, and chronic obstructive pulmonary disease in four (6.2%) patients. There was no lower limb in the CEAP 0 and CEAP 1 before the procedure. The preoperative CEAP classification of the lower limbs was C2 in 13 (16.9%) patients, C3 in 57 (74.0%) patients, and C4a in seven (9.1%) patients. The cyanoacrylate adhesive was successfully applied to all 77 lower extremities with GSV insufficiency. The mean GSV diameter was 7.5±1.8 (range, 5.5 to 14) mm. The mean reflux time was 3.4±0.7 (range, 2 to 4.5) sec. The mean length of the treated GSV was 26.3±3.3

Table 1. Baseline demographic and clinical characteristics and intraoperative data of patients

	n	%	Mean±SD	Median	Min-Max
Age (year)			53.7±16.8	55.0	18-89
Sex					
Female	42	64.6			
Male	23	35.4			
Primary symptom					
Pain	54	70.1			
Varicosity	69	89.6			
Swelling	64	83.1			
Feeling of heaviness	59	76.6			
Burning sensation	34	44.2			
History of compression therapy	17	22.1			
CEAP classification					
C2	13	16.9			
C3	57	74.0			
C4A	7	9.1			
Proximal GSV diameter (mm)			7.5±1.8	7.0	5.5-14.0
Reflux time (sec)			3.4±0.7	3.5	2-4.5
Occluded GSV length (cm)			26.3±3.3	26.0	20-33
Procedure time (min)			14.0±1.8	14.0	9-21

SD: Standard deviation; Min: Minimum; Max: Maximum; CEAP: Clinical, etiological, anatomical, pathophysiological; GSV: Great saphenous vein.

(range, 20 to 33) mm. The mean procedural time was 14.0±1.8 (range, 9 to 21) min. Baseline demographic, clinical, and intraoperative data of the patients are shown in Table 1.

The total occlusion rate was 97.4% at 12 months. No polymerized cyanoacrylate extending to the common femoral vein after the procedure was observed. Deep vein thrombosis and pulmonary embolism were not seen after the procedure. The proximal partial recanalization of the GSV was observed in two lower limbs at the postoperative one and three months. The preoperative diameters of these GSVs were 14 mm and 12.4 mm, respectively. No additional recanalization was observed at 6 and 12 months. After the procedure, inflammation was observed in one patient and phlebitis reaction on the treated GSV trace was observed in two patients. No serious adverse events or paresthesia were observed.

The CEAP scores of the patients at 12 months were CEAP 0/1. The mean VCSS improved from 5.9±1.5 at

Table 2. Pre- and postoperative VCSS and AVVQ changes

	VCSS			AVVQ score		
	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max
Preoperatively	5.9±1.5	6.0	3.0-13.0	15.4±3.6	15.0	10.0-24.0
2nd day	3.0±1.0	3.0	2.0-10.0			
1st month	1.8±0.6	2.0	1.0-5.0	7.7±1.7	7.0	4.0-12.0
3rd month	1.3±0.6	1.0	1.0-5.0	4.1±1.2	4.0	2.0-8.0
6th month	0.9±0.5	1.0	0.0-2.0	3.5±0.9	3.0	2.0-6.0
12th month	0.8±0.6	1.0	0.0-2.0	3.8±0.7	4.0	2.0-5.0
P according to Friedman test for repeated measurements	0.000 <0.001			0.000 <0.001		
Pairwise comparison (Bonferroni test)	Everyone of 6 consecutive measurement is different from any others, with significance.			Everyone of 6 consecutive measurement, except 1st month with 12th month and 6th month and 12th, is different with significance.		

VCSS: Venous Clinical Severity Score; AVVQ: Aberdeen Varicose Vein Questionnaire; SD: Standard deviation; Min: Minimum; Max: Maximum.

baseline to 0.8±0.6 at 12 months. The mean AVVQ score improved from 15.4±3.6 at baseline to 3.8±0.7 at 12 months after the procedure. In terms of the VCSS and AVVQ scores, significant improvements were observed at all time points of the post-procedural follow-up, compared to baseline (p<001 for all). The mean pre- and postoperative VCSS and AVVQ scores are given in Table 2.

DISCUSSION

Chronic venous insufficiency may cause adverse effects on the quality of life of patients and a decrease in work performance. The NBCA adhesive, which has been recently applied endovenously in the treatment of CVI and varicose veins, has been used for the treatment of arteriovenous malformations, and gastric and duodenal varicose veins for about two decades.[14,15] In an experimental study in a rabbit model, histopathological examination after the injection of cyanoacrylate adhesive into the vessel showed that acute inflammatory effect and chronic granulomatous foreign body reaction occurred, and eventually fibrosis developed.[16]

Cyanoacrylate adhesive was first used by Almeida et al.[9] in saphenous vein failures in humans. In the study, the saphenous vein occlusion rate in 38 patients with symptomatic saphenous vein failure was found to be 92% at 12 months of follow-up. The mean amount of endovenous cyanoacrylate was 1.3±0.4 (range, 0.6 to 2.3) mL, and the occlusion rate was 100% at 48 h of follow-up. The rate of phlebitis after the procedure was 15.8%. The mean VCSS improved from 6.1±2.7 to 1.5±1.4 at 12 months of follow-up. At 12 months, 50% of the legs had no visible varicosities and 25% had limited varicosities.[9] In a multi-center study including 70 patients conducted in Europe on the use of cyanoacrylate adhesives in GSV insufficiency, the GSV occlusion rate was 92.9% at 12 months of follow-up.[10] In addition, the mean VCSS improved from 4.3±2.3 to 1.1±1.3 at 12 months. The AVVQ scores also improved from 16.3 to 6.7. After the procedure, pain was observed in 8.6% of the patients.[10] In a randomized study comparing cyanoacrylate and radiofrequency ablation (RFA) in GSV failure, the occlusion rate was 99% in cyanoacrylate treatment and 96% in RFA treatment at three months of follow-up.[17] In addition, the VCSS improved from 5.5 to 1.9 and the AVVQ score improved from 18.9 to 11.6 at three months. Phlebitis was observed in 22 of 108 patients in whom cyanoacrylate was used.[17]

In the present study, we applied a special formula of NBCA with dimethyl sulfoxide using the VenaBlock® Venous Closure System in the treatment of GSV insufficiency. We applied low-viscosity NBCA continuously. The NBCA of the VenaBlock® creates a rapid polymerization reaction which occludes the target vein within 5 sec. Due to rapid polymerization, it is important to provide it continuously. Another important point is to apply pressure on the vein following the NBCA administration. In our study, the GSV closing rate was 97.4% at 12 months of follow up. The post-procedural GSV occlusion rate was higher than previous studies, in which different devices and techniques were used,[9,10,17] owing to the low-viscosity and pharmacological structure of cyanoacrylate, and the device and technique used in the present study. In addition, tumescent anesthesia was not required in cyanoacrylate embolization as in thermal ablation. Since cyanoacrylate was polymerized very quickly due to our device and technique, deep venous thrombosis and pulmonary embolism were not observed due to the rapid closure of GSV, short procedure time and the application of the appropriate amount of pressure on SFJ. In our study, the impact of the VenaBlock® NBCA treatment on the quality of life was demonstrated by the AVVQ scoring systems. As expected, the AVVQ scores improved significantly after the procedure and during follow-up, compared to the baseline, in parallel with the anatomical success of the embolization of the GSVs in patients treated with cyanoacrylate and these results are consistent with clinical studies involving cyanoacrylate. Similarly, at 12 months of follow-up, the mean VCSS was 0.8±0.6 and improved significantly compared to baseline, which is consistent with previous reports.[9,10]

The phlebitis reaction seen along the treated vein within three to seven days after the procedure in our patients was mild and transient. This reaction was successfully treated with non-steroidal anti-inflammatory drugs. The incidence of phlebitis (2.6%) was lower than the rates found in the study of Almeida et al.[9] and Morrison et al.[17] Moreover, the absence of thermal ablation resulted in no burn, pigmentation, or paresthesia after the procedure. In addition, during cyanoacrylate embolization, there was no pain, hematoma, vein wall perforation, skin burns, ecchymosis, skin pigmentation, swelling, nerve injury, or arteriovenous fistula formation. The inflammatory reaction occurred in the first week in one patient which was treated with anti-inflammatory drugs.

In our study, proximal partial recanalization occurred in two patients at one and three months

during follow-up. This situation may be related to perforator and minor venous branch insufficiency, and the insufficient dose of cyanoacrylate for the target vein diameter. On the other hand, cyanoacrylate adhesive system was found to be a less effective technique related to the occlusion rate among five different treatment techniques for a GSV diameter of ≥10 mm in a comparative study.[18] In addition, the mean GSV diameter of ≥8 mm was found to be a significant predictor for recanalization in a prospective study.[19] Moreover, the American Venous Forum recommended the use of cyanoacrylate for veins with a diameter of <12 mm.[20] Although the treatment success is more favorable in smaller vein diameters, cyanoacrylate seems to yield a higher recurrence rate in large GSV diameters.[21,22] In our study, the proximal partial recanalization of GSV was observed in two lower limbs (preoperative GSV diameter: 12.4 mm and 14 mm). Therefore, our study results are consistent with the findings in the literature. Besides, in such cases, we cannot speculate whether the compression stockings can prevent the treatment failure. Additional studies are needed to identify the GSV closure rates in the long-term and the possibility of increasing the effectiveness of embolization of GSV with cyanoacrylate by exposing venous side branches with a large diameter during the initial procedural visit and by providing their potential treatment.

Compression stockings for one week after the EVTA procedures for the treatment of GSV insufficiency are recommended for reducing postoperative pain and edema, despite the lack of strong evidence.[11] Additionally, there is no evidence for the extended use of compression after endovenous ablation of varicose veins according to a recent meta-analysis.[23] There is no recommendation either, regarding the use of compression stockings after cyanoacrylate treatment in the current guidelines.[11,24] Therefore, no compression stockings were applied after the procedure in our study according to previous large-scale studies.[12,13]

Although our study has some limitations including retrospective and single-center design with a relatively small sample size, the results are significant. Of note, findings of pioneering studies related to cyanoacrylate adhesive applied endovenously in GSV insufficiency appear to be promising. However, comparative, prospective, long-term, randomized studies are still needed to confirm these findings.

In conclusion, endovenous treatment of GSV insufficiency with NBCA adhesive is a rapid and effective method and significantly improves the quality of life of patients. In addition, this procedure does not require the use of tumescent anesthesia and compression stockings with a relatively short procedural time.

Declaration of conflicting interests

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