Cardiovascular Topics

Evaluation of clinical results of esmarch bandage application in giant saphenous vein closure during endovenous glue ablation

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Abstract

Background: In recent years, the endovenous technique has been presented as a good alternative to surgery in the treatment of patients with lower extremity varicose veins. However, its effectiveness in very advanced saphenous vein diameters is controversial. In this study, we investigated the results of an endovenous glue ablation closure system applied with an esmarch bandage in saphenous veins with very large diameters.

Methods: Eighty-nine patients who were operated on for varicose veins were divided into three groups according to their saphenous vein diameters: less than 10 mm (group 1), between 10 and 15 mm (group 2), and larger than 15 mm (group 3). Endovenous closure was performed with n-butyl cyanoacrylate in all patients. An esmarch bandage was applied during the procedure to all patients, except for the group with a diameter of less than 10 mm. This group underwent the standard procedure. All patients were followed up for six months after the procedure and postoperative symptoms, complications and closure rates were recorded.

Results: There was complete closure of all veins in the first month postoperatively. While no thrombophlebitis was observed in group 3, thrombophlebitis was detected in two patients in groups 1 and 2. In the third month, minimal saphenofemoral reflux was observed in two (4.2%) patients in group 1 and in one (4.3%) in group 2. In the sixth month, minimal saphenofemoral reflux was detected in three (6.3%) patients in group 1 and in one (4.3%) in group 2. No residual leakage was observed in group 3 ($p = 0.001$). In all groups, the severity score regressed significantly in the postoperative sixth month. However, the most significant symptomatic regression was observed in group 3, which had the largest saphenous diameters and we used an esmarch bandage during closure ($p = 0.000$).

Conclusion: Our findings support the idea that the application of an esmarch bandage during endovenous closure improves clinical outcomes, especially in saphenous veins with larger diameters.

Keywords: varicose veins, endovenous closure, esmarch bandage, large diameter, postoperative outcomes

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Although the incidence of chronic venous insufficiency increases with age, it is an important pathology affecting all age groups.[1] In addition to having certain risk factors, such as gender, family history, obesity, pregnancy, sedentary lifestyle, and being constantly exposed to smoke and smoking, it also occurs in the postphlebitic process after deep venous thrombosis.[1,2] This pathology, which impairs an individual's quality of life, also causes active future workforce losses.[2,3]

Increased venous blood pressure affects deep and superficial veins. Venous insufficiency causes pain in the legs, restlessness, night cramps, and later in life, varicose veins and oedema develop under the skin, with poor cosmetic results. In more advanced stages, it results in ulcers due to stasis dermatitis. Therefore, it should be diagnosed and treated with the appropriate treatment methods.[2,3]

In the early period of disease, medical treatment and compression are usually sufficient. However, additional interventional treatment methods are needed in the future.[4] Surgical treatment has been developed for the great and small saphenous veins, which are usually superficial veins. If there is no venous leakage in the deep veins, prevention of leakage in the superficial veins relieves the symptoms to a great extent. For removal of the saphenous vein, surgical treatment was previously performed as open surgery and/or its ligation in the saphenofemoral region. However, due to poor cosmetic results, the need for general or spinal anaesthesia, and a long postoperative recovery period, over time, surgery has been replaced by endovenous closure systems.[5,6]

The most commonly used endovenous techniques are endovenous laser ablation (EVLA), radiofrequency ablation (RFA) and chemical ablation. Although successful operations

have been reported with all methods, preferences vary in different clinics due to usage differences and accessibility.[6,7] EVLA and RFA, which have been used in the past, have been presented as a useful alternative to surgery, as they have good cosmetic results and successful mid- and long-term results.[6,7] However, studies show that these systems are based on heat energy and require tumescent anaesthesia during the procedure, and that heat-related tissue damage occurs during ablation. This has led to the search for alternative methods.[8,9]

N-butyl cyanoacrylate (NBCA) ablation methods, which are offered as a good solution to this issue and are gaining popularity, are easy to apply under local anaesthesia and do not cause surrounding tissue damage.[9] Studies have reported successful treatment rates with this method, as well as with EVLA and RFA.[10] However, all these endovenous methods are generally used in the treatment of insufficiency of saphenous veins less than 10 mm in diameter. Although successful results have been reported in larger vessels, discussions on the subject continue.

In this study, a new technique was described to investigate the success level of NBCA ablation of saphenous veins larger than 15 mm, and the aim was to determine the outcome. The pre-ablation bandaging technique was used as a new technique and its clinical results were evaluated in the light of the literature.

Methods

This study was designed as a prospective, cross-sectional study. After the steps of the study were determined, ethics committee approval was obtained by applying to the clinical research local ethics committee (approval no. 18-04/21). All steps of the study were carried out in accordance with good clinical practices and the principles of the Declaration of Helsinki. Informed consent was obtained from all patients.

Patients were included in the study if they had superficial venous insufficiency at the saphenofemoral junction in a Doppler ultrasonography performed at the cardiovascular surgery clinic, a great saphenous vein diameter of over 6 mm and they opted for surgery. The vessel diameters of all patients were confirmed by an independent surgeon using colour Doppler (Philips Lumify linear transducer, Philips Healthcare, Cambridge, MA). Patients with a vessel diameter of less than 5.5 mm, a history of previous vascular surgery, chronic or acute deep venous thrombosis and those who did not agree to participate in the study were excluded from the study.

A total of 89 patients were included in the study. Patients were divided into three groups according to great saphenous vein diameter: less than 10 mm (group 1, $n = 48$), between 10 and 15 mm (group 2, $n = 23$), and over 15 mm (group 3, $n = 18$). Ablation treatment with NBCA was planned for each group. Also, an esmarch bandage was applied during the vessel ablation procedure in all patients with a vessel diameter greater than 10 mm. The standard treatment was used for those with a vessel diameter of less than 10 mm.

After the patient was covered with a sterile drape, the saphenous vein was located with venous Doppler at the knee level. After local anaesthesia, a 7F sheath was inserted into the saphenous vein using the Seldinger method. Under the guidance of ultrasound, the saphenous vein diameter was measured under the junction (Fig. 1A, B) and a Venex (Vesta Medical Devices, Ankara, Turkey) catheter was advanced up to the saphenofemoral junction. The catheter was then retracted 2 cm distal to the junction, and compression was applied to the saphenofemoral junction with an ultrasound probe. The diffuse saphenous vein was closed by applying NBCA through a catheter.

This process was the same in all groups. However, in groups 2 and 3, with a large saphenous diameter, after the catheter was placed at the saphenofemoral junction, it was completely wrapped with an esmarch bandage from the knee to the groin before starting the closure procedure (Fig. 1C, D).

The ablation procedure was then initiated. The aim was to reduce the vessel diameter of patients with large vessel diameters using compression and to de-bloat the operation area. Varicose side branches were removed by mini-flebectomy. After the procedure, the extremities were completely wrapped with an elastic bandage and the patients were observed for one hour and then discharged.

All patients were called for routine one-, three- and six-month follow up, and vessel diameters (Fig. 1E, F), clinical complaints and additional conditions (needle puncture ecchymosis, thrombophlebitis) under ultrasound were recorded. Revised venous clinical severity score (rVCSS) values before and after the procedure were processed into the data, as described in the previous literature.[11]

Statistical analyses

Statistical analyses were performed using a software program (SPSS v 22.00, IBM, Armonk, NY). Continuous variables are presented as the mean ± standard deviation (SD) and ranges. Ratios were compared using the chi-squared test. After using the Mann–Whitney *U*-test as a *post hoc* analysis, the difference between postoperative findings was evaluated using the Kruskal–Wallis *H*-test. The rVCSSs were compared using a one-way analysis of variance (ANOVA). The statistical significance was accepted at $p < 0.05$.

Results

When the demographic distribution of the groups was evaluated, it was observed that the patients in the group with a saphenous vein diameter over 15 mm (group 3) were older ($p = 0.010$), and the saphenous vein diameters were larger in the females ($p = 0.001$). Table 1 summarises the demographic distribution of the groups. Also, as expected, both clinical classification and rVCSS scores were higher in patients in group 3, where the saphenous veins had the largest diameters. The mean saphenous vein diameter was 6.4 ± 2.4 mm in group 1, 12.3 ± 1.6 mm in group 2 and 18.4 ± 3.8 mm in group 3.

Additional mini-phlebectomy was performed in 12, 10 and 10 patients in groups 1, 2 and 3, respectively (Table 1). When the groups were compared in terms of postoperative complications, thrombophlebitis was found in two patients in groups 1 and 2 and not in any in group 3.

No recanalisation or residual leakage was observed in any group in the first month after the operation. At the third month, minimal saphenofemoral reflux was observed in two (4.2%) patients in group 1 and in one (4.3%) in group 2. At the sixth month, minimal saphenofemoral reflux was detected in three

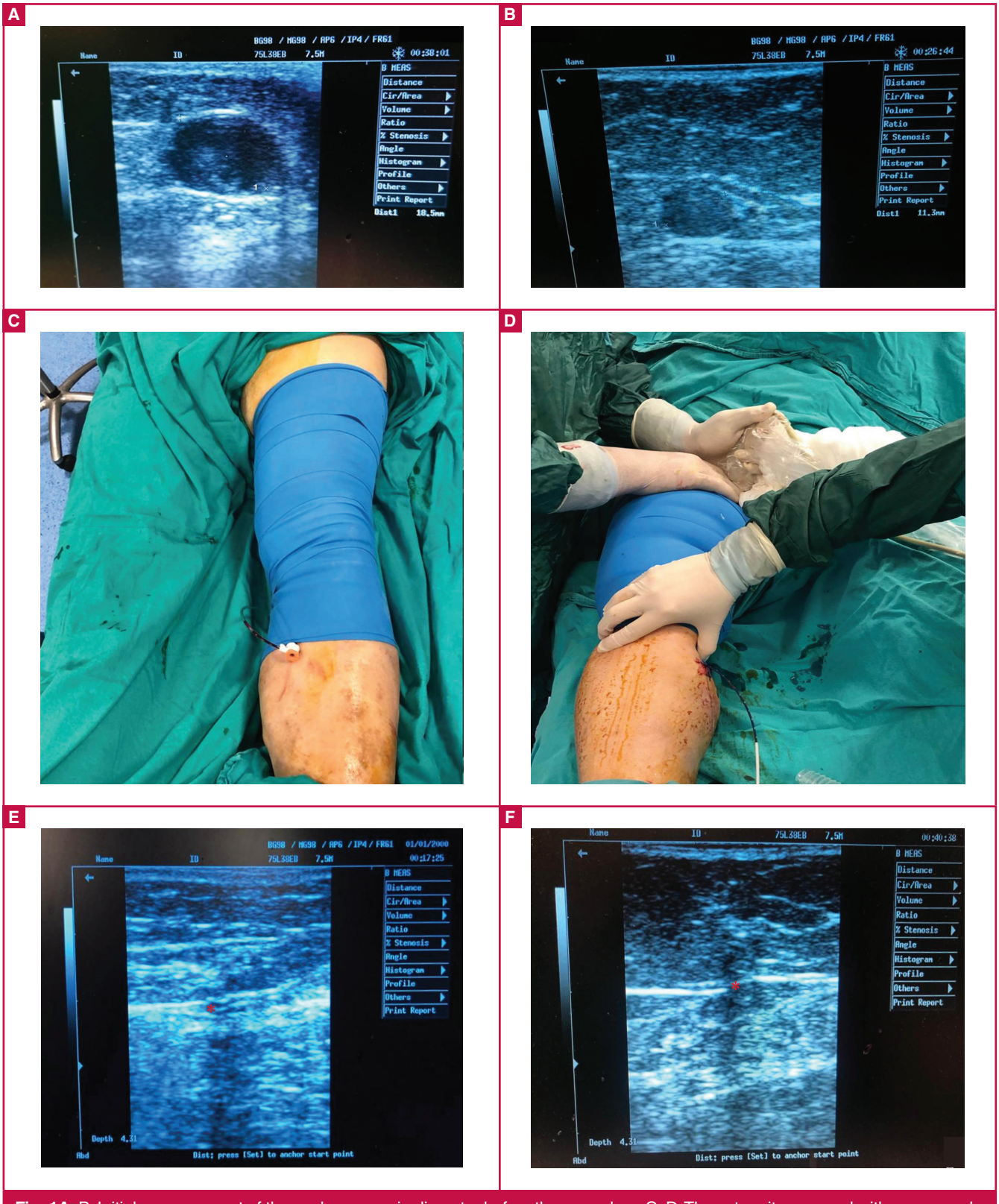

Fig. 1A, B. Initial measurement of the saphenous vein diameter before the procedure. C, D. The extremity wrapped with an esmarch bandage to provide total compression of the vein during closure. E, F. Re-evaluation of vein diameter and closure after the first month (the red star shows a closed saphenous vein and halo area).

(6.3%) patients in group 1 and in one (4.3%) in group 2. No residual leakage was observed in group 3 ($p = 0.001$).

In all groups, rVCSS regressed significantly at six months postoperatively ($p = 0.000$). However, the most significant symptomatic regression was observed in group 3, which had the largest vein diameters and we had used an esmarch bandage

Table 1. Demographic and clinical variables in the groups

Variables	*Group 1* (n = *48*)	*Group 2* (n = *23*)	*Group 3* (n = *18*)	p-*value**
Age	36.44 ± 18.03	37.22 ± 10.99	47.83 ± 10.66	0.010
Gender (female), *n* (%)	13 (27.0)	15 (65.2)	12 (66.6)	0.001
CEAP				
C2	15	1	7	0.000
C3	32	3	4	
C4	1	17	4	
C5[a]	0	2	3	
Severity score[b]	5.1 ± 2.6	5.6 ± 2.1	5.8 ± 1.8	0.000
Great saphenous vein diameter	6.4 ± 2.4	12.3 ± 1.6	18.4 ± 3.8	0.000
Removal of branch veins, *n* (%)	12 (25.0)	10 (43.4)	10 (55.5)	0.000

[a]C5: clinical classification 5 (same columns were combined); [b]analysed by using one-way analysis of variance.
*Kruskal–Wallis *H*-test and Mann–Whitney *U*-test as *post hoc* analysis, $p < 0.05$ is significant.
CEAP: clinical, aetiological, anatomical and pathophysiological classification of venous disorders.

Table 2. Postoperative clinical outcomes in the groups

Outcomes	*Group 1* (n = *48*)	*Group 2* (n = *23*)	*Group 3* (n = *18*)	p-*value**
Thrombophlebitis, *n* (%)	2 (4.2)	2 (8.7)	0 (0)	0.001
Ecchymosis, *n* (%)	3 (6.2)	2 (8.7)	1 (5.5)	0.448
Insufficient closure or continuing reflux 1st month, *n* (%)	0 (0)	0 (0)	0 (0)	–
Insufficient closure or continuing reflux 3rd month, *n* (%)	2 (4.2)	1 (4.3)	0 (0)	0.021
Insufficient closure or continuing reflux 6th month, *n* (%)	3 (6.3)	1 (4.3)	0 (0)	0.001
Postoperative severity score[b]	0.9 ± 1.4	1.2 ± 1.0	1.7 ± 1.3	0.000

[b]Analysed using one-way analysis of variance.
*Kruskal–Wallis *H*-test and Mann–Whitney *U*-test as *post hoc* analysis, $p < 0.05$ is significant.

during closure ($p = 0.000$). Postoperative findings are compared in Table 2.

Discussion

Our study is the first to investigate the effects of the esmarch bandage in the endovascular treatment of varicose veins. Postoperative results according to vein diameters during endovascular closure with NBCA are presented. It was shown that the use of an esmarch bandage in the closure of venous structures over 10 mm increased the chance of postoperative success and could prevent additional complications, such as ecchymosis or phlebitis.

The treatment of incompetent saphenous vein insufficiency with closure techniques using NBCA has been presented as a very current and effective method.[10,12] Eroğlu *et al*. found that NBCA treatment success was similar to that of the endothermal ablation technique after two years of follow up.[13] Also, compared to other endovascular techniques, it has been reported as an advantage that it can be applied with local anaesthesia without requiring tumescent anaesthesia, leading to less postoperative pain and faster recovery.[10,12]

However, it has been shown that a larger saphenous vein diameter was associated with a high recurrence rate among three different vessel sizes, even when using the endothermal ablation technique for the treatment of venous insufficiency.[14] Similarly, in the literature, higher recurrence rates in patients with large pre-operative diameters of the saphenous vein were emphasised during NBCA treatment techniques.[15,16]

In a study by Chan *et al*., 8-mm and larger diameters were defined as the independent predictor of recanalisation for saphenous veins closed with NBCA.[17] Kubat *et al*. published their results on four different techniques, namely high ligation + stripping (HLS), RFA, NBCA closure and EVLA procedures at 980- and 1.470-nm wavelengths, for the treatment of saphenous vein insufficiency with a diameter over 10 mm. In this study, the authors found that NBCA treatment seemed to yield a higher recurrence rate in large saphenous vein diameters.[15]

In another study, the NBCA closure technique was also reported to yield high rates of recanalisation in patients with vein diameters greater than 10 mm.[16] In our study, although the saphenous vein diameter was less than 10 mm in group 1 where the classical technique was performed (without the use of an esmarch bandage), higher recanalisation rates were detected, while higher closure rates were found in groups 2 and 3 in which an esmarch bandage was used.

In another report on saphenous vein insufficiency, the post-procedure thrombosis rate was emphasised. In this study, it was found that the most basic and only risk factor for superficial thrombus formation after ablation was a saphenous vein diameter over 10 mm.[18] These and similar data led to the addition of saphenous vein diameter to the inclusion or exclusion criteria in studies investigating planned endovenous closure techniques, and studies can be planned accordingly.[19]

Thrombosis has been shown to be one of the most common complications in endovenous techniques, although the overall complication rate is low, according to data from another study.[20] In fact, it has been reported that the rate of partial thrombosis after intervention is higher for various reasons in patients with larger vessel diameters. Thrombophlebitis and venous thrombosis have been reported as the most prominent postoperative complications after ablation with chemical agents, such as polydicanol.[21] With EVLA, RFA and other techniques, these complications were found to be more common in patients with saphenous vein diameters greater than 8 mm.[21]

According to results obtained from the studies, the rate of thrombotic events is between zero and 8% in techniques such as EVLA and RFA, which are based on heat transfer, regardless of vessel diameter, while similar clinical results have been reported with NBCA.[22] From the results of the study by Bissacco *et al*. with 918 patients, the major complications after saphenous vein ablation with NBCA were reported as 4.8% postoperative pain and 2.1% superficial vein thrombosis.[23] In our study, while the rates of thrombophlebitis were consistent with the literature in groups 1 and 2, thrombophlebitis was not found in group 3, where the saphenous vein diameter was the largest, and an esmarch bandage was used.

In a study by Favard *et al*., in which NBCA was applied to the intravascular area, it was observed that NBCA stimulated the local intravascular inflammatory response by triggering thrombosis and causing sclerosis but it did not cause an advanced reaction.[24] It has been suggested that exposure to blood cells further enhances the inflammatory process.[25] Other factors have been suggested, such as the proximity of the vein to the skin and the diameter of the vein.[26]

Although the exact effect of NBCA has not been clarified, it has been hypothesised to be a type IV delayed hypersensitivity reaction caused by a foreign substance, rather than a localised inflammation. In pre-clinical studies, it has been shown that exposure of the endothelium to NBCA resulted in subacute vasculitis and chronic granulomatous foreign body reactions, depending on the concentration of the substance. Fibrosis and partial recanalisation related to the density of the contact with the substance were detected around the exposure area.[25–27]

Extremity wrapping with an esmarch bandage is a method that is frequently used during orthopaedic interventions to prevent exsanguination and to keep the surgical field clean by providing compression of the extremity vascular structures and blocking blood flow to the extremity. In this way, both venous and arterial blood flow is stopped and vascular structures are reduced in diameter.[28,29]

The European Society of Vascular Surgery guidelines reported that studies have shown a closure rate of 98% in saphenous vein diameters up to 20 mm.[30] However, there are studies reporting that a saphenous vein diameter over 8 mm increased the recanalisation rate and that the increased diameter was associated with a longer stump remnant.[30]

In our study, the esmarch bandage used during the closure of the saphenous veins with NBCA, stopping the blood flow and reducing the venous structure with compression, was associated with agent exposure and decreased phlebitis, recanalisation and ecchymosis rates.

Limitations

The main limitation of the study is that it was conducted on a limited number of patients based at a single centre. Larger cohort studies are needed. Another important limitation is that the study lacked groups using other techniques, such as EVLA and RFA. With further studies including these groups, the hypothesis needs to be investigated that wrapping with esmarch may be effective by blocking blood flow in the vessel to be treated, and reducing the diameter of the vessel.

Conclusion

Wrapping the vessel extremity with an esmarch bandage during NBCA ablation of the saphenous veins seemed to both increase the success rate of the procedure and reduce adverse events, such as postoperative ecchymosis and thrombophlebitis. This method could be more successful than other endovenous closure techniques. However, comprehensive data are needed to obtain more detailed and precise data.

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