

Use of N-Butyl Cyanoacrylate Embolization in the Treatment of Venous Insufficiency Case Series[§]

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Venöz Yetmezlik Olgu Serilerinin Tedavisinde N-Butil Siyanoakrilat Embolizasyonunun Kullanımı

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ABSTRACT

Objective: Objective of this study is to analyze the results of patients who underwent embolization treatment with n-butyl cyanoacrylate in vena saphena magna due to chronic venous insufficiency (CVI).

Methods: 241 patients who underwent saphena ablation due to venous stasis between January 2017 and 2020 at Bozok University Medical Faculty Hospital were included in the study. Cyanoacrylate embolization (CAE) was performed on 249 extremities in 241 patients with vena saphena magna (VSM) diameter above 5.5 mm and saphena-femoral junction reflux duration longer than 0.5 s as measured by Color Doppler Ultrasonography (CDU). Patients were followed up with clinical examination at post-op Day 7 post-op and CDU scans at Months 1 and 6.

Results: Mean age was 42.7±12.35 years, and the average diameter of the saphenous vein was 8.21±2.5. The operation time was 15.27 minutes on average and the patients were discharged on the same day. Thrombophlebitis developed in 12 (4.81%) of our cases; cellulitis in 4 patients (1.60%); and erythema on the skin over the trace of the saphenous vein in 20 patients (8.03%) and improved with medical treatment. Partial recanalization was identified in 8 VSMs (3.21%) in CDU controls at Month 6. No patients developed deep vein thrombosis or neurological complications.

Conclusion: Shorter operation and discharge durations, high VSM obliteration, low complication rates are the outstanding properties of CAE. The fact that the technique is limited with patients with tortuous veins as is the case with all procedures requiring a catheter has not been able to completely exclude conventional surgery.

Keywords: venous insufficiency, n-Butyl cyanoacrylate, embolization

ÖZ

Amaç: Bu çalışmanın amacı, kronik venöz staz nedeniyle vena safena magnada n-butil siyanoakrilat ile embolizasyon tedavisi gören hastaların sonuçlarını analiz etmektir.

Yöntem: Ocak 2017 - 2020 tarihleri arasında Bozok Üniversitesi Tıp Fakültesi Hastanesi'nde venöz yetmezlik nedeniyle safena ablasyonu yapılan 241 hasta çalışmaya dahil edildi. Renkli Doppler Ultrasonografi (RDU) ile ölçülen vena safena magna (VSM) çapı 5,5 mm'nin üzerinde ve safena-femoral bileşke reflü süresi 0,5 saniyeden uzun olan 241 hastada 249 ekstremiteye siyanoakrilat embolizasyonu (SAE) uygulandı. Hastalar ameliyat sonrası 7. Günde klinik muayene ve 1. ve 6. Aylarda RDU taramaları ile takip edildi.

Bulgular: Ortalama yaş 42,7 ± 12,35 yıl ve ortalama safen ven çapı 8,21 ± 2,5 idi. Operasyon süresi ortalama 15,27 dakika idi ve hastalar aynı gün taburcu edildi. Olgularımızın 12'sinde (% 4,81) tromboflebit gelişti; 4 hastada (% 1,60) selülit; 20 hastada (% 8,03) safen ven izi üzerinde ciltte eritem ve medikal tedavi ile düzeldi. Altıncı ayda RDU kontrollerinde 8 VSM'de (% 3,21) kısmi rekanalizasyon tespit edildi. Hastalarda derin ven trombozu veya nörolojik komplikasyon gelişmedi.

Sonuç: Daha kısa operasyon ve deşarj süreleri, yüksek VSM obliterasyonu, düşük komplikasyon oranları SAE'nin öne çıkan özellikleridir. Tekniğin, kateter gerektiren tüm prosedürlerde olduğu gibi, kıvrımlı damarları olan hastalarla sınırlı kullanım alanına sahip olması, geleneksel cerrahiye tamamen dışlayamamıştır. CAE tedavisi, uygun vasküler yapılara sahip hastalar için başarılı sonuçları ile umut verici bir geleceğe sahiptir.

Anahtar kelimeler: venöz yetmezlik, n-Bütül siyanoakrilat, embolizasyon

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INTRODUCTION

Venous insufficiency and the resultant spider veins of the lower extremity are diseases that impair the quality of life by hindering daily activity. It is observed in 25-33% of women and 10-20% of men ^[1]. The most common symptoms of chronic venous insufficiency (CVI) are cramps, pain, prostration, burning sensation, swelling, itching, paresthesia, and fatication in the legs, and these symptoms notably impair the quality of life of the patients. Not only can CVI emerge as a cosmetic problem but it might also lead to serious skin problems such as skin ulcers ^[2]. Surgical techniques have been the preferred method in the treatment of venous insufficiency for more than a hundred years. However, the complications induced by surgical treatment and anesthesia and the frequency of postoperative recurrence have created the need for treatment methods that are alternative to surgical treatment ^[3,4]. Laser, radiofrequency ablation, foam cyclo-therapy and Cyanoacrylate embolization (CAE) are the methods employed. Despite being a commonly used minimally invasive method, foam cyclo-therapy has side effects such as high relapse rates, air embolism, pulmonary embolism, deep vein thrombosis, and headache ^[5]. Endovenous laser or radio-frequency ablation requires tumescent anesthesia. Tumescent anesthesia might lead to such side effects as prolonged operation times, postoperative pain, destruction of afferent nerves, and ecchymosis ^[6]. Tumescent anesthesia is not required in the CAE application. The operation carried out is the embolization of a vena saphena magna (VSM) with reflux that is longer than 0.5 seconds and vasodilatation of 5.5 mm and above. When n-Butyl Cyanoacrylat (NBCA) embolization comes into contact with blood or tissue, it ensures vein occlusion by forming a strong tissue bond via polymerization. Maximum bond strength is achieved 2.5 minutes later on average. It has a high viscosity and adequate elasticity. It reduces the risk of embolization in the deep veins through its rapid polymerization, it does not cause limitation of movement with its elasticity and therefore, it increases the comfort of the patient ^[7,8]. We intend to investigate and assess the results of patients who underwent CAE.

MATERIAL and METHOD

241 patients who underwent saphenous vein ablation due to venous insufficiency between January 2017 and 2020 at Bozok University Medical Faculty Hospital were included in our study. Preoperative venous insufficiency was evaluated via a CDU scan in all of the cases. Patients with VSM diameters of 5.5 mm and above and saphenofemoral reflux periods longer than 0.5 seconds as measured by CDU scans were accepted as indicated patients.

The study is retrospective and data were obtained in the form of file scanning. In our clinic, the criteria for NBCA and VSM embolization were determined as described below, and therefore they represent the criteria in our study.

Criteria for inclusion in the study; Patient age ≥ 19 years to ≤ 75 years; VSM reflux ≥ 0.5 seconds; VSM vein diameter between ≥ 5.5 and ≤ 17 mm; and CEAP classification C2-C5.

Criteria for exclusion from the study; Tortuous VSM, DVT and PE history; target vasodilatation more than 17 mm; symptomatic peripheral arterial disease, cyanoacrylates allergy; and pregnancy.

Eight major symptoms which are preoperative fatigue, swelling, itching, formication, cramps, pain, paresthesia and burning sensation were examined. Patients were followed up with clinical examinations at Day 7 post-op and with CDU scans at Months 1 and 6. At Month 6, a survey indicating the eight symptoms, which the patients were inquired about in the postop period, as Full Recovery, Mild Recovery, No Recovery and Aggravated was conducted.

Surgical Technique

The interventions were performed as sterile in the operating room under general anesthesia. The intervention was carried out by inserting a cannula with a CDU-guided VSM percutaneous method. The endovascular intervention set was placed into the VSM, the marked catheter was pushed until 3 cm behind the saphenofemoral junction, and the location of the catheter was detected via CDU. The solution was prevented from entering into the deep venous system by way of pressing on the femoral junction

before administering cyanoacrylates. A conduction catheter was prepared before administering NBCA into the vein. The catheter was prepared for use by triggering. The conduction catheter was pulled towards the distal at a speed of 2 cm/s while the trigger was being pulled for 5 seconds. 0.03 cc/cm NBCA polymer was introduced into the lumen with five-second triggers. The saphenous vein was embolized in this manner. Concurrently, the vein was compressed for 10 s. Saphenous vein segments were controlled with Doppler after the process.

Statistical Analyses

All statistical analyses were conducted SPSS system version 22.0 (SPSS, IBM, Chicago, USA). Descriptive statistics are presented as means standard deviation (SD) or by frequency percentages.

RESULTS

All patients were symptomatic, and 150 (62.2%) of them were women and 91 (37.8%) were men and the average age was 42.7±12.35 years. 119 of 249 lower extremities of 241 patients who underwent CAE were left legs and 130 were right legs. The patients were observed to be between C2 and C5 in the CEAP classification. The demographics of the patients are given in Table 1.

The mean diameter of the saphena was 8.21±2.5mm. The duration of the operation was 15.2 minutes on average, and the patients were discharged on the same day. The postoperative discharge time was 47.3 minutes, and the mean NBCA amount per case was approximately 1.42±0.5 ml. 12 (4.81) of our cases had thrombophlebitis, 4 patients (1.60%) had cellulitis, 20 patients (8.03%) had ecchymoses on the skin over the trace of the saphenous vein, and 19

Table 1. Demographic data.

	n (%)
Gender	241
Female	150 (62.2)
Male	91 (37.8)
Clinical, Etiological Anatomical, Pathophysiological (CEAP) Classification	249
C2	32 (12.86)
C3	146 (58.63)
C4	62 (24.89)
C5	9 (3.62)
Age	42.7±12.35
Right Leg	119 (47,79)
Left Leg	130 (52.20)

Ybü: Yoğun bakım ünitesi

Table 2. Findings and complications.

	n (%)
Mean diameter of the saphena (mm)	8.21±2.5
Mean operation duration (min)	15.2
Thrombophlebitis	12 (4.81)
Cellulitis	4 (1.60)
Ecchymosis	20 (8.03)
Venous recanalization	8 (3.21)

patients (7.63%) had pain, but all were improved by medical treatment. During the CDU follow-up examination at Month 6, partial recanalization was identified in 8 VSMs (3.21%). None of our patients developed deep vein thrombosis or neurological complications. In the survey conducted at Month 6, a significant decrease was determined in the symptoms.

Obliteration was achieved in 247 (99.19%) of 249 operations during the CDU follow-up examination at Month 1 postop, and obliteration was achieved in 241 cases (96.78%) at Month 6. The results of the preoperative survey inquiring the eight symptoms

Table 3. Symptoms and the ratio of changes.

Preop Symptoms n (%)	Full recovery at Month 6 postop n (%)	Partial Recovery at Month 6 postop n (%)	No Recovery at Month 6 postop n (%)	Aggravated Symptoms at Month 6 postop n (%)
Cramps 218 (87.5)	163 (74.7)	44 (20.18)	11 (5.04)	-
Pain 247 (99.1)	169 (68.4)	64 (25.91)	14 (5.66)	-
Itching 81 (32.5)	36 (44.4)	41 (50.61)	4 (4.93)	-
Fatigue 223 (89,5)	140 (62.7)	74 (33.18)	9 (4.03)	-
Paresthesia 82 (32.9)	29 (35.3)	48 (58.53)	5 (6.09)	-
Formication 57 (22.8)	21 (36.8)	32 (56.14)	3 (5.26)	1 (1.75)
Burning 79 (31.7)	32 (40.5)	40 (50.63)	7 (8.86)	-
Swelling 206 (82.7)	127 (61.6)	73 (35.43)	6 (2.91)	-

were recorded and it was repeated in the follow-up examination carried out 6 months later.

No increase was observed in the symptoms except for the postoperative sensation of formication in one patient. While the ratio of patients stating no change in the symptoms was between 2.91% and 8.86%, the ratio of those stating full recovery was 44.4% and 68%. The highest full recovery ratio was reported by 169 patients (68%) as pain relief. The symptoms and the ratio of changes are given in Table 3.

DISCUSSION

Chronic venous insufficiency (CVI) is a widespread condition leading to great socio-economic impacts due to its high prevalence [9]. Unless treated, it progresses and leads to venous hypertension. As a result, it leads to venous ulcers and complications that may cause loss of extremities [10]. Recently, the use of noninvasive techniques instead of conventional surgery has increased in the treatment of CVI. These techniques are laser, radiofrequency ablation, foam cyclo-therapy, and NBCA embolization. Among these methods, foam cyclo-therapy is not recommended as a first-line treatment for truncal reflux lesions in the treatment guidelines [11]. On the other hand, the laser and radiofrequency ablation techniques require the use of tumescent anesthesia. Multiple injections carried out to administer tumescent causes ecchymosis, pain and neuropathic damage [12]. As Almeida et al. used NBCA in VSM insufficiency for the first time, it is no more required to use tumescent anesthesia [13]. However, thermal ablation methods are likely to have significant complications such as postoperative pain, ecchymosis, paresthesia and particularly, vein wall ruptures [14]. The most severe possible complication in the CAE technique is the occurrence of the embolization in the deep vein system outside VSM. To avoid this complication, the saphenofemoral junction is monitored via Doppler ultrasonography while administering NBCA and it is closed by the dense pressure applied with a probe. Again, the catheter through which the active ingredient is administered must be at a certain distance from the junction. There are different opinions concerning the safe distance in the literature. Although studies suggesting a distance of 5cm are available [15,16], the predominant practice is 3 cm [17,18]. In our

case series, the safe distance was adopted as 3 cm and none of our patients developed deep vein thrombosis. We also believe that three centimeters are a sufficient distance. Complications were thrombophlebitis by 4.81%, cellulitis by 1.60% and ecchymosis by 8.03% which occurred within the first one month that may be referred to as the early period and they recovered with medical treatment.

In the studies and meta-analyses conducted, the rates of occlusion with CAE were reported to be between 92-99% [19]. In our study, the rate of occlusion was found to be 99.19% in the CDU in Month 1, and 96.78% during the follow-up at Month 6. In a series consisting of 318 patients in our country, the mean operation duration was reported as 10.03±3.9 min [20]. Our mean operation duration was 15.27 min. All patients were discharged on the same day, and our mean postoperative discharge duration was 47.39 min. Studies comparing NBCA and other ablation techniques detected shorter surgery duration and shorter hospital stays in the NBCA group [21]. In a study carried out by Bozkurt et al. and consisting of 310 patients, results of EVLA (n:256) and NBCA (n:154) were compared. According to this study, in the NBCA group the pain during the operation, the operation duration and ecchymoses were observed statistically significantly less on Day 3. While permanent or temporary paresthesia developed by 4% in the EVLA group, it was not observed in the NBCA group. The rates of occlusion at Months 1, 3 and 12 were better in the NBCA group for all three follow-up levels and they were only significant at Month 1 [22]. During the follow-up of our study at Month 6 postop, full recovery of the symptoms of the patients was between 44.4% and 68%. The highest rate of full recovery was reported by 169 patients (68%) as pain relief.

The limitation of the number of cases in our study and the evaluation of the improvement in their complaints by the patients themselves may include subjective interactions.

CONCLUSION

Shorter operation and discharge durations, high VSM obliteration, low complication rates are the outstanding properties of CAE. The fact that the

technique is limited with patients with tortuous veins as is the case with all procedures requiring a catheter has not been able to completely exclude conventional surgery. CAE treatment has a promising future with its successful outcomes for patients with eligible vascular structures.

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