Our Results of Endovenous N-Butyl Cyanoacrylate Treatment in Varicose Veins

Variköz Venlerde Endovenöz N-Bütil Siyanoakrilat Tedavisi Sonuçlarımız

Erdem ÇETİN¹ 0 0000-0002-4065-9016 Ertan DEMİRDAŞ² 0 0000-0002-7854-3481 Gökhan EROL² 0 0000-0003-4632-2606 Hüseyin SİCİM² 0 0000-0003-3430-3862 Hakan KARTAL² 0 0000-0003-4539-0228 Gökhan ARSLAN² 0 0000-0001-6123-0457

 ¹Karabuk University Faculty of Medicine Department of Cardiovascular Surgery, Karabuk
 ²Gulhane Training and Research Hospital Department of Cardiovascular Surgery, Ankara

Sorumlu Yazar Corresponding Author Hüseyin SİCİM drhuseyinsicim@gmail.com

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ABSTRACT

Aim: In this study, we aimed to evaluate the results of endovenous N-Butyl Cyanoacrylate (NBCA) technique which is a non-tumescence endovenous ablation technique in patients with varicose veins.

Material and Methods: A total of symptomatic 542 patients with single or bilateral saphenofemoral failure who presented to our center between April 2014 and August 2016 were included in the study. NBCA was applied to 657 lower extremities of 542 patients, 115 of whom were bilateral. The patients had C2, C3, C4, C5, C6 venous insufficiency according to CEAP classification. Vena saphena magna (VSM) diameter was at least 5.5 mm at the knee level, at least 6 mm at the saphenofemoral junction (SFJ) level, and reflux time was 2 seconds or longer.

Results: The mean CEAP classification of 657 lower extremities was 3.1 ± 0.6 , the VSM diameter was 6.7 ± 1.1 mm at the knee level, 8.3 ± 2.1 mm at the SFJ, the procedure time was 15.2 ± 2.9 minutes, and the hospital stay was 1.7 ± 0.6 hours. At 6 months follow-up, only 7 (1.1%) partial recanalization of VSM, 1 (0.2%) deep vein thrombosis in the popliteal vein in the lower limb, and 9 (1.4%) thrombophlebitis in the distal 1/3 segment at over the knee of VSM healing with medical treatment. All of the procedures were completed without any complications.

Conclusion: Newly developing techniques rapidly replace traditional methods and increase patient comfort. NBCA; It has become an effective method among endovenous ablation therapies with its technical advantages, high success rates in early and midterm.

Keywords: Cyanoacrylates; endovenous ablation therapy; venous insufficiency; laser therapy.

ÖZ

Amaç: Bu çalışmada kliniğimizde variköz venli hastalarda non-tümesan endovenöz ablasyon tekniği olan endovenöz N-Bütil Siyanoakrilat (NBSA) tekniğinin sonuçlarının değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntemler: Nisan 2014 ve Ağustos 2016 tarihleri arasında merkezimize başvuran tek ya da iki taraflı safenofemoral venöz yetmezliği olan, semptomatik 542 hasta çalışmaya dahil edildi. Yüz on beşi bilateral olmak üzere 542 hastanın toplam 657 alt ekstremitesine NBSA uygulandı. Hastaların CEAP sınıflamasına göre C2, C3, C4, C5, C6 venöz yetmezliği mevcuttu. Vena safena magna (VSM) çapı diz seviyesinde en az 5,5 mm, safenofemoral bileşke (SFB) düzeyinde ise en az 6 mm ve reflü süresi 2 saniye veya daha uzundu.

Bulgular: Altı yüz elli yedi alt ektremitenin ortalama CEAP sınıflandırması 3,1±0,6, VSM çapı diz seviyesinde 6,7±1,1 mm, SFB'de 8,3±2,1 mm, işlem süresi 15,2±2,9 dakika ve hastanede kalış süresi 1,7±0,6 saat idi. Altı aylık takipte sadece 7 (%1.1) VSM'de parsiyel rekanalizasyon, 1 (%0.2) alt ekstremitede popliteal vende derin ven trombozu ve 9 (%1.4) VSM'de dizüstü 1/3 distal kesiminde medikal tedavi ile düzelen tromboflebit gözlendi. Yapılan işlemlerin tamamı herhangi bir komplikasyon oluşmadan tamamlandı.

Sonuç: Yeni gelişen teknikler hızla geleneksel yöntemlerin yerini alarak hasta konforunu arttırmaktadır. NBSA; tekniğe has avantajları, erken ve orta dönemdeki yüksek başarı oranları ile endovenöz ablasyon tedavileri arasında etkin bir yöntem olarak yerini almıştır.

Anahtar kelimeler: Siyanoakrilat; endovenöz ablasyon tedavi; venöz yetmezlik; lazer terapi.

INTRODUCTION

Lower extremity chronic venous insufficiency (CVI) and varicose veins are an important disease that is very common in the society and causes serious losses in quality of life and labor force. In many studies, it has been reported that CVI is seen in 25-50% of the adult individual population (1-3). The most common symptoms of CVI are pain in the leg, fatigue, burning sensation, swelling, itching and tingling and these symptoms significantly impair the quality of life of patients. CVI may occur only as a cosmetic problem in the clinic or may cause serious complications such as venous ulcers. The rate of serious complications varies between 20-40% (3,4). The CVI is classified worldwide by the Clinical Etiologic Anatomic Pathophysiologic (CEAP) classification (Table 1). Surgical techniques have been the preferred method for the treatment of CVI over a hundred years. However, complications due to surgical treatment and anesthesia, and frequent recurrence after treatment have necessitated alternative treatment methods for surgical treatment. In a recent meta-analysis, it has been shown that endovenous treatments are effective methods with acceptable success rates in symptomatic saphenous vein insufficiency (5). In the last 20 years, there have been very serious developments in the diagnosis and treatment of CVI. The most important of these is the use of color Doppler ultrasonography (CDUS) in the diagnosis and treatment of venous insufficiency. With these advances, endovenous laser ablation (EVLA), radiofrequency ablation (RFA), foam sclerotherapy and recently endovenous treatment methods with N-butyl cyanoacrylate (NBCA) have been developed under CDUS. These methods, which are applied by CDUS with local anesthesia, have become widespread all over the world and have largely replaced surgical treatment. Because of its ease of application and pleasant results, NBCA has been popular day by day and it is a liquid embolizer that has been known for a long time, it reacts very quickly when it comes into contact with blood and it quickly causes inflammation (6,7). This effect has been frequently used in the embolic treatment of vascular malformations and intracerebral aneurysms, as well as in the treatment of gastrointestinal bleedings, mesenteric aneurysms, arteriovenous fistulas, bone cysts, and has been frequently used in the treatment of saphenous vein deficiency in recent years (8-10). In this study, we aimed to evaluate the results of endovenous NBCA technique which is a non-tumescence endovenous ablation technique in varicose vein patients in our clinic.

MATERIAL AND METHODS

A total of 542 patients with single or bilateral saphenofemoral insufficiency who presented to Karabük Medikar Hospital Cardiovascular Surgery Clinic between April 2014 and August 2016 were included in the study. The study was approved by the local Ethics Committee of Düzce University Medical Faculty (01.04.2019 - 2019/70). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki. All patients were evaluated according to the CEAP classification and the patients were examined for the presence of reflux with venous lower extremity CDUS and vena saphena magna (VSM) diameters before the operation. Patients with chronic or acute thrombophlebitis, deep venous insufficiency, severe peripheral arterial disease, history of deep venous thrombosis (DVT), immobility, systemic infection, focal venous aneurysm enlargement were excluded.

Patients with VSM diameter greater than 5.5 mm and reflux current 2 sec or longer were included in the study. VSM diameter is at least 5.5 mm at knee level, 6 mm at saphenofemoral junction (SFJ) level and 2 sec or longer reflux time; VSM isn't severely tortiose; according to the CEAP classification are in the stages C2, C3, C4, C5, C6; NBCA was applied to 657 lower extremities of 542 patients with 115 bilateral. Demographic data of the patients are given in Table 2. NBCA isn't applied to the patients who had chronic or acute thrombophlebitis, deep venous insufficiency, severe peripheral arterial disease, DVT history, immobility, systemic infection, focal venous aneurysm enlargement, and other endovenous ablation techniques were used. All patients were evaluated according to CEAP classification. Before the procedure; seven symptoms including pain, cramps, swelling, itching, feeling of fatigue, burning sensation, tingling, numbness were investigated in the patients. Elastic bandage was applied to all patients after the procedure. During the first 24 hours, the bandage was not opened and it was recommended to use mid-pressure varicose stockings for two months. The patients were discharged on the same day and the patients were offered frequent mobilization on the same day. The patients were called for polyclinic control at the first postoperative week and CDUS control at the first and sixth months. In the sixth month after the procedure, a questionnaire was applied to the patients in order to evaluate the above seven symptoms as full recovery, mild improvement, no change and increase.

Technic

The lower extremities of the patients were sterilized and covered. Because the procedure was performed under CDUS guidance, the probe was placed in a sterile camera case. Patients were hydrated by intravenous 1000 cc of 0.9% saline due to the difficulty of puncturing non-dilatable VSMs. VSM was punctured under local anesthesia under US guidance from just below the knee joint and from 1/3 proximal of cruris. A 7F vascular sheath

 Table 1. Clinical Etiologic Anatomic Pathophysiologic (CEAP) Classification

C (Clinic)	E (Etiology)	A (Anatomy)	P (Pathophysiology)	
C0 = Normal	Ec = Congenital	As = Superficial veins	Pr = Reflux	
C1 = Spider / reticular veins	Ep = Primer	Ad = Deep veins	Po = Obstruction	
C2 = Varicose veins	$\mathbf{E}\mathbf{s} = \mathbf{Seconder}$	Ap = Perforane veins		
C3 = Edema		-		
C4 = Skin changes				
C5 = Healing ulcer				
C6 = Active ulcer				

was inserted into the VSM over the guidewire. The J guide wire was inserted to the SFJ through the 7F vascular sheath with CDUS guidance. After the microdelivery catheter was located 3 cm distal to the SFJ, a total of 2 cc NBCA injector was applied to each 10 cm VSM segment with 0.3 cc NBCA at 5 sec intervals. After the procedure, saphenous venous occlusion was checked with CDUS and the procedure was completed.

Statistical Analysis

The statistical evaluation of this study was performed using the statistical program SPSS v.11.5 (SPSS Inc, Chicago, IL). Descriptive statistics were given as mean±standard deviation for continuous variables and, as frequency and percentage for categorical variables.

RESULTS

In our clinic, the gender distribution of the patients who underwent endovenous NBCA treatment due to VSM deficiency were 341 female (62.9%), 201 male (37.1%) and the mean age of patients was 46.0 ± 9.6 (Table 2). The mean CEAP classification of the 657 lower extremities was 3.1 ± 0.6 (range, 2 to 5), the mean VSM diameter was 6.7±1.1 mm at the knee level, 8.3±2.1 mm at the SFJ, and the total procedural duration was 15.2±2.9 min (range, 7 to 34 min). The mean duration of hospital stay was 1.7 ± 0.6 h (range, 40 min to 4h). At 6 months of follow-up of 657 lower extremities, no recanalization was observed in any VSM but only 7 (1.1%) partial recanalization was observed in the lower extremity VSM. DVT developed in 1 (0.2%) lower extremity popliteal vein. Thrombophlebitis was observed in 9 (1.4%) lower extremity, which was treated by medical treatment in the 1/3 distal part of the VSM. No allergic reaction, infection, ecchymosis and hematoma were observed in any patient. Table 3 shows the symptoms (pain, cramps, swelling, itching, feeling of fatigue, tingling, burning sensation, numbness) according to the questionnaire forms of the patients in the postoperative sixth month.

DISCUSSION

If CVI is not treated, it causes venous hypertension by progressing, resulting in complications that may cause loss of extremities with venous ulcers. Among the symptoms of CVI; Cosmetic problems, pain, itching, fatigue sensation, superficial thrombophlebitis, dermatitis and skin ulcers can be found. Endovenous ablation therapy in VSM deficiency is rapidly becoming an alternative to surgical treatment. In the treatment of endovenous ablation, there is a significant decrease in the morbidity related to surgery, complications related to anesthesia, loss of labor and hospital cost rates (11,12). When deciding on the method of treatment, cosmetic results are important for patients as well as for the treatment of symptoms. In the treatment of VSM deficiency, less invasive sclerotherapy, RFA and EVLA treatment methods are used. Endovenous ablation treatments are easier to apply and have been used more frequently than surgery because of better cosmetic results (13). Endovenous ablation therapies have been shown to be a reliable and effective method with high success rate in symptomatic VSM deficiency in many studies. No significant difference was found between EVLA and RFA technical and clinical results. It is reported that occlusion success in the saphenous vein ablated in both techniques is over 90% in the first year and 90% in the third and fifth years (14,15). Rasmussen et al. (16) performed a randomized controlled trial comparing EVLA, RFA, surgical stripping and foam sclerotherapy in 580 lower extremities in the treatment of symptomatic VSM reflux. As a result of the study, the rate of recanalization was found to be 16.3% in the first year after foam sclerotherapy, 4.8% after EVLA and surgical stripping, and 5.8% after RFA. Due to high recurrence, foam sclerotherapy is not preferred by many centers for the purpose of closing VSM. Previous studies have shown that

Table 2. Demographic data of patients undergoing NBCA

Age	46.0±9.6				
Gender, n (%)					
Female	341 (62.9%)				
Male	201 (37.1%)				
Preoperative mean VSM					
diameter (mm)					
Knee level	6.7±1.1 mm				
At the SFJ	8.3±2.1 mm				
CEAP	3.1±0.6 (range, 2 to 5)				
Total procedural duration	15.2±2.9 min (range, 7 to 34 min)				
Hospitalization time	1.7±0.6 h (range, 40 min to 4 h)				
Descriptive statistics were shown as number of patients and (percent) or					
mean±standart deviation, VSM: Vena saphena magna; CEAP: Clinical					
etiologic anatomic pathophysiologic, NBCA: N-Butil Civanoacrilat					

Symptoms	Before the		After the Procedure				
	Procedure	Full healing	Partial healing	No change	Deterioration		
Pain	657 (100)	479 (72.9)	171 (26.0)	7 (1.1)	-		
Cramp	583 (88.7)	460 (78.9)	113 (19.4)	10 (1.7)	-		
Swelling	614 (93.4)	492 (80.1)	121 (19.7)	1 (0.2)	-		
Itching	308 (46.9)	146 (47.4)	138 (44.8)	24 (7.8)	-		
Fatigue feeling	632 (96.2)	335 (53.0)	291 (46.0)	6 (0.9)	-		
Numbness	571 (86.9)	253 (44.3)	318 (55.7)	-	-		
Tingling	476 (72.5)	257 (54.0)	219 (46.0)	-	-		
Burning sensation	438 (66.7)	225 (51.4)	212 (48.4)	1 (0.2)	-		

Descriptive statistics were shown as number of patients and (percent), NBCA: N-Butil Ciyanoacrilat

RFA and EVLA may cause complications such as burns on the skin, hematoma, superficial nerve damage, as well as ecchymosis, hematoma, pain and sensory nerve damage due to tumescence anesthesia (5,17-19). In this study, we found that none of these complications seen in RFA and EVLA were seen in patients who underwent NBCA. Another important result we found is that NBCA is an effective method for the elimination of symptoms of patients. Again in a recent study comparing EVLA and NBCA, the rates of occlusion in the 12th month were 92.2% in EVLA and 95.8% in NBCA (20). In the same postoperative study, early pain, ecchymosis, thrombophlebitis, skin pigmentation and paresthesia were less common in NBCA (20). Gürkan et al. (21) reported that EVLA of great saphenous vein with a radial laser fiber by using a 1470 nm diode laser and automated pull back system is a safe and efficient treatment option. In our study, the 6-month occlusion rate was 98.9% and was consistent with the literature. As in most randomized clinical trials, endovenous treatments are as effective as surgery. In addition, cosmetically, endovenous treatments are easier to apply, hospital costs are lower than surgery because of the advantages such as lower labor force loss and less complications due to surgery and anesthesia, because they are less invasive methods than surgery. We believe that there is an advantage for patients. As a result, we think that NBCA has advantages such as lack of risk of thermal damage, no need for anesthesia and ease of application, and it will have an important place among endovenous methods in the treatment of venous insufficiency with early results.

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