The comparison of radiofrequency and Cyanoacrylate embolization therapy in vena saphena magna ablation

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Abstract

Aim: Chronic venous insufficiency is a frequent and disabling illness causing loss of life quality and labor. In this study, we aimed to compare the cyanoacrylate embolization and radiofrequency methods in vena saphena magna ablation therapy.

Material and methods: Two hundred twenty patients with symptomatic venous insufficiency were involved in this study between November 2015 and January 2020 in Bozok University faculty of medicine cardiovascular surgery department. Patients were grouped into two groups. Group 1 included patients who were applied radiofrequency, and Group 2 included patients who underwent cyanoacrylate embolization. Preoperatively, Doppler ultrasound showed venous reflux and VSM diameter in all patients. Patient with non-tortuous veins and VSM diameter of more than 5.5 mm and a reflux duration of more than 0.5 seconds in the saphenofemoral junction were taken into consideration. This study included 110 cases in each group with similar demographic characteristics. After discharge, patients were called for control after one week, and in the first and sixth months they were evaluated with Doppler ultrasound.

Results: A month later, during the procedure in Doppler USG control, we found that VSM in 108 out of 110 patients (%98.18) was obliterated in the RF group. In the cyanoacrylate embolization (CAE) group, VSM was totally obliterated in all patients. Six months later, obliteration was 107 (%97.27) in RF and 109 (%99.09) in the cyanoacrylate group. In a month, %8.18 ecchymosis, %0.9 cellulitis and %1.81 thrombophlebitis were seen in the RF group. Complications in the cyanoacrylate group were ecchymosis in %10.9, cellulitis in %2.72 and trombophlebitis in %0.9. The duration of the procedure was 32.14 minutes in the RF group and 15.32 minutes in the CAE group. Preoperatively, the patients were asked 8 questions about the symptoms. After six months, the same questions were asked and answers were compared with the previous ones. In both groups, the recovery was similar.

Discussion: Although the classical surgical procedure of venous insufficiency is a successful method, it has complications. When deciding the therapy method, cosmetic results should be kept in mind. Also, the shorter operation duration affects the choice. Frequently applied methods are EVLA, RFA, foam sclerotherapy, and CAE. RF and CAE technics were effective as classical surgery in chronic venous insufficiency. Effectiveness and complication rates were not different, but the shorter duration of procedure makes CAE more advantageous.

Keywords
Radiofrequency ablation; N-Butyl Cyanoacrylate; Embolization; Venous insufficiency

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Introduction

Chronic venous insufficiency and varicose veins are disabling illnesses causing loss of life-quality and labor. Its prevalence is 6%25-50 among the adult population [1]. Pain, venous claudication, swelling, itching are the most encountered symptoms of venous insufficiency. As it may cause only cosmetic problems, ulceration can be a serious symptom of venous insufficiency [2]. In parallel with medical and technical improvements, alternatives to the surgical treatment of chronic venous insufficiency have begun to be used. These methods can be classified as endovenous laser ablation (EVLA), radiofrequency ablation (RFA), foam sclerotherapy, and cyanoacrylate embolization (CEA). EVLA was first used in 1999. It prevents the reflux in the saphenofemoral junction by producing thermal injury that causes occlusion of saphenous vein endothelium [3]. Side effects as postoperative ecchymosis, paresthesia, pain, thermal injury to skin, fibrosis can be seen [4]. Although foam sclerotherapy is a widely used, minimally invasive method, its disadvantages are higher recurrence rate, air embolism, pulmonary embolism, deep venous thrombosis, and headache [5]. It is not recommended as a primary therapy in trunkal vein reflux in guidelines [6]. RFA is a process of bipolar energy formed by sound waves. Endothelium contracts as a result of heat produced by the electrode upon contact with the endothelium. [7] CAE is an ablation technic that does not need tumescent anesthesia. IV application of N-butyl cyanoacrylate results in hardening by polymerization. After injection and application of pressure to the vein, the vessel closes. [8] In our clinic, we compared the results of examination of complications.

Material and Methods

Two hundred twenty patients with symptomatic venous insufficiency who applied to Bozok University Medical Faculty Cardiovascular Surgery Department between November 2015 and January 2020 were enrolled in the study. Demographic properties are classified in Table 1. Patients aged between 19 to 70 and those with Venasaphena magna diameter between 5.5 to 16 mm identified by Doppler examination, patients with a reflux period in saphenofemoral junction of more than 0.5 seconds, C2-C5 in CEAP classification, and veins without tortuosity were included in the study. Exclusion criteria were symptomatic peripheral arterial disease, deep venous thrombosis, and pulmonary embolism history, pregnancy, and cyanoacrylate allergy. Patients were grouped into two groups. RFA was applied to the first group and CEA was applied to the second. Each group consisted of 110 patients with similar demographic characteristics. Preoperatively, each patient was examined with Doppler ultrasound in order to see reflux and vein diameter. All of them were admitted to the hospital after one week for examination and at the first and sixth months, they were examined with Doppler ultrasound. Questions were asked about eight symptoms, including pain, tiredness, swelling, itching, cramps, tingling, neuropathic symptoms, and a burning sensation, and six months later, at the control visit they were asked again about symptoms, and changes were noted.

Surgical Procedures

Cyanoacrylate Embolization

N-butyl cyanoacrylate is a fast glue used in industry and medicine. After contact with moisture, blood and tissue, its monomer form rapidly polymerizes, and within 10 seconds tension force increases. It stabilizes in one to three minutes. In last stage, tension force increases logarithmically. With Doppler ultrasound guidance, saphenous vein catheterization was made and 5F introducer sheath was replaced. The J-Guide wire was inserted and after reaching to SFJ, a 4F catheter was placed 3 cm distal to the SFJ. The guide wire was pulled out and the syringe mechanism was attached. Compression was applied to the SFJ with an ultrasound probe. The catheter was pulled 2 cm per second and 0.3 ml of glue was inserted simultaneously with every shot. After 10 seconds of compression to SFJ, saphenous vein track obliteration was checked with Doppler ultrasound.

Radiofrequency Ablation

In order to prepare a tumescent solution, we added 50 ml of lidocaine, 1 ml of adrenal and 10 mEq NaHCO3 into 1000 ml NaCl. A 7 F vascular sheath was inserted in VSM, and an RFA fiber catheter was placed at least 2 cm away from SFJ under Doppler guidance. Later, the tumescent solution was injected throughout VSM. For every 7 cm of VSM, 10-40 watt and 120 OC ablation was applied twice every 20 seconds.

Results

In the first month, during Doppler examination, in the RFA group, 108 out of 110 were found to be obliterated, while in CEA group, all were completely obliterated. At the sixth months, obliteration in the RFA group was 107 (%97.27) and in the

| Table 1. Demographic data of the patients |
|----------------|----------------|
| Gender         | Radiofrequency Ablation Group 1 | Cyanoacrylate Embolization Group 2 |
|                | n(%)                             | n(%)                              |
| Female         | 67(60,90)                         | 62(56,36)                         |
| Male           | 43(39,09)                         | 48(45,63)                         |
| Age            | 39,27±12                          | 42,58±14                          |
| Right leg      | 51(46,36)                         | 54(49,10)                         |
| Left leg       | 59(53,63)                         | 56(50,90)                         |
| CEAP classification |                 |                                   |
| C2             | 91(82,72)                         | 32(29,09)                         |
| C3             | 12(10,90)                         | 57(51,81)                         |
| C4             | 65(54,5)                          | 191(17,27)                        |
| C5             | 10(0,90)                          | 211(18,1)                         |
| Saphenous mean diameter (mm) | 9,2±6,32                       | 8,2±2,6                           |

| Table 2. Results and complications |
|----------------|----------------|
| Radiofrequency Ablation 1. Group n (%) | Cyanoacrylate Embolization 2. Group n (%) |
| Ecchymosis             | 5(8,18) | 12(10,90) |
| Cellulitis             | 1(0,90) | 3(2,72)   |
| Thrombophlebitis       | 2(1,81) | 1(0,90)   |
| Hematoma               | 5(4,54) | 21(18,1)  |
| Paresthesia            | 3(2,72) | 1(0,90)   |
| Recanalized vein       | 7(6,36) | 5(4,54)   |
| Saphenous vein mean diameter (mm) | 6,8±2,1 | 8,2±2,6   |
| Mean operation duration (min) | 32,14   | 15,32     |
CAE group it was 109 (%99.09). Within the first month, %8.18 ecchymosis, %0.9 cellulitis, %1.81 thrombophlebitis was seen in the RFA group. In the CAE group, %10.9 ecchymosis, %2.72 cellulitis, %0.9 thrombophlebitis was seen as a postoperative complication. VSM diameter was 6.8±2.1 in the RFA group and 8.21±2.6 in the CAE group. The mean operation duration was 32.14 in RFA and 15.32 in the CAE group. Preoperatively, 8 questions were asked again to see the differences. Six months later, the same questions were asked and noted. No significant difference was detected.

**Discussion**

Although the classical surgical procedure of venous insufficiency is a successful method, it has complications such as infection on the incision side, lymphoedema, hemorrhagia, arterial and venous injury, deep venous thrombosis, keloid scar. [9] When deciding the therapy method, cosmetic results should be kept in mind. Besides surgery, sclerotherapy, RFA, EVLA (endovenous laser ablation) are the therapy methods. Endovenous ablation is easy and better cosmetic results make it the first choice for surgery. [10,11] Also, the short operation duration affects the choice. Frequently applied methods are EVLA, RFA, foam sclerotherapy, and CAE. Foam sclerotherapy may cause amaurosis fugax, migraine, allergic reaction, confusion. Therefore, it is not recommended as the primary method for truncal reflux lesions. [12,6] Both EVLA and RFA obliterate the vein as a result of thermal injury. In CAE embolization, vascular embolization is obtained by the chemical action of n-butyl cyanoacrylate. There are many studies comparing the treatment of chronic venous insufficiency with surgical and catheter-based techniques. Van Den Bos conducted 119 research on 12320 patients. The success rate was %78 with classical surgery, %77 with foam sclerotherapy, %84 with RFA and %94 with EVLA. [13] In our country, Bozkurt and his team investigated 310 patients, comparing EVLA (156) and CAE (154), and a statistically short operation period, less pain, fewer ecchymosis in CAE were found significant. Permanent and temporary paresthesia was % 4 in EVLA, while it was not observed in CAE. [14]

In our study, we compared RFA and CAE techniques. Demographically they were similar. The shorter operation period made CAE more preferable. The aforementioned operation duration differences, in our opinion, were caused by the application of tumescent anesthesia. In the literature, deep venous thrombosis (%1-3), thrombophlebitis (%1-2), sensorial damage (%1-3), hyperpigmentation (%1-2), skin burn (less than %1) are noted [15].

There was no deep venous thrombosis in our study. The most frequently seen complication was ecchymosis, which was cured medically. At the follow-up visit six months later, there was no significant difference between the groups. RFA and CAE techniques for minimally invasive therapy of venous insufficiency are as effective as surgery. No significant difference in effectiveness and complications were detected, but a shorter operation period makes CAE more preferable.

**Table 3. Comparison of symptoms after therapy**

| Preoperative Symptoms | Postoperative total cure at sixth months (%) | Postoperative subtotal cure at sixth months (%) | Postoperative no change in symptoms compared to preoperative at sixth months (%) |
|-----------------------|--------------------------------------------|-----------------------------------------------|--------------------------------------------------------------------------------|
| **RFA** | **CAE** | **RFA** | **CAE** | **RFA** | **CAE** | **RFA** | **CAE** |
| Pain | 110(100) | 109(99.09) | 94(85.45) | 92(84.40) | 109(99.09) | 12(11,00) | 6(5,45) | 5(4,58) |
| Burning sensation | 67(60.90) | 74(67.27) | 42(62.68) | 37(77.02) | 62(65,88) | 14(18,91) | 9(13,43) | 3(4,05) |
| Tiredness | 81(73,61) | 86(78.18) | 53(65,43) | 49(56,97) | 24(29,62) | 29(33,72) | 4(4,95) | 8(9,30) |
| Itching | 65(59,09) | 52(47,27) | 34(52,30) | 22(42,30) | 19(29,23) | 24(46,15) | 12(18,46) | 6(11,53) |
| Swelling | 32(29,09) | 46(41,81) | 17(55,12) | 19(51,81) | 21(55,19) | 20(43,47) | 8(20,00) | 7(15,21) |
| Cram | 59(53.61) | 50(45,45) | 35(59,32) | 24(40,00) | 21(55,19) | 22(50,00) | 5(0508) | 4(8,00) |
| Numbness | 41(37,27) | 49(44,54) | 12(29,26) | 16(32,65) | 9(21,95) | 20(48,78) | 23(46,93) | 23(46,93) |
| Tingel | 28(25,45) | 33(30,00) | 9(32,74) | 11(33,33) | 4(14,28) | 8(24,24) | 15(33,57) | 14(42,42) |

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