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ORIGINAL ARTICLE

A Novel Modified Technique with a Combination of Percutaneous Embolization with N-Butyl Cyanoacrylate and High Ligation of Saphenous Vein: a Preliminary Report

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Abstract

Chronic venous insufficiency (CVI) is defined as a condition affecting the venous system of lower extremities. Different treatment options are used for the treatment of this pathological condition, which impairs quality of life, especially in later stages. Surgical options are used in the case of failure with conservative treatment and pharmacological methods. There are numerous surgical techniques used in the treatment of venous insufficiency. Each of these techniques has its advantages and disadvantages. New hybrid methods are being developed to overcome adverse effects and possible complications such as deep vein thrombosis, phlebitis, and infections. In the present study, we aimed to present the preliminary results of a combination of percutaneous embolization of SV with n-butyl cyanoacrylate (NBCA) and high ligation, which is a novel modified method that we have developed. A total of 47 patients, aged between 28 and 62 years and diagnosed with chronic venous insufficiency, were included in the study. The patients were evaluated with a Comprehensive Classification System For Chronic Venous Disorders, and Venous Clinical Severity Score (VCSS). Patients' demographic features such as age and gender, and clinical features such as CEAP classes, VCSSs, and vena saphena magna VSM diameters were recorded. All patients were treated with a novel modified hybrid technique including Venablock embolization system (Invamed RD, Ankara, Turkey) and surgical high ligation of the greater SV. In addition, patients' preprocedural, intraprocedural, and postprocedural period follow-up data were recorded and retrospectively analyzed. According to the CEAP classification, 38 patients (80.8%) were classified as C3, six patients (12.8%) as C4, and three patients (6.4%) as C2. CEAP class was C3 in majority (38/47) of the patients, with 22 (46.8%) female and 22 (53.2%) male patients in C3 class. The mean preoperative VCSS of the patients was calculated as 8.83 ± 1.31 and the mean postoperative VCSS was calculated as 2.85 ± 0.71. The mean postoperative VCSS was statistically significantly lower than the mean preoperative VCSS ($p < 0.05$). The technical success rate was found as 100%. None of the patients developed complications or side effects. We suggest that this novel method is efficient and safe in the treatment of chronic venous insufficiency because it eliminates the need for general anesthesia with short operation time and adhesion of all branches of the saphenous vein, thus preventing possible complications.

Keywords Chronic venous insufficiency · High ligation · N-butyl cyanoacrylate · Saphenous vein

Introduction

Chronic venous insufficiency (CVI) is defined as a condition affecting the venous system of lower extremities. The main manifestation of CVI is ambulatory venous hypertension, which causes various pathologies such as pain, edema, skin changes, and ulcerations [1, 2]. The same clinical manifestations may have resulted from different pathogenic mechanisms including incompetent valves, venous obstruction, muscle pump dysfunction, or a combination of them.

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There are various risk factors associated with the development of CVI, and perhaps the most common one is a strong family history [3]. The other risk factors include a history of phlebitis, female gender, pregnancy, and prolonged standing. Venous insufficiency may influence both young and elderly patients. It is estimated that about 27% of the adult population in the USA have chronic venous insufficiency. CVI impairs overall quality of life and leads to a considerable work loss especially at later stages [4].

The diagnosis of chronic venous insufficiency is based on physical examination, differential diagnosis, and non-invasive and invasive testing. Among these methods, venous duplex imaging (VDI) is still the most commonly used method in the diagnosis of CVI. The other methods include computed tomographic or magnetic resonance venography and intravascular ultrasonography. The disease is classified using the clinical, etiological, anatomical and pathophysiological (CEAP) classification, which was developed in an international consensus conference [5]. The most commonly used section of the CEAP classification is the clinical (C) section. This classification is a valuable tool for objective evaluation of CVI, providing a system to standardize CVI classification, which emphasizes on the cause, and distribution of the manifestations of the disease [6].

The main indications for the treatment of chronic venous disease include symptoms (pain, discomfort, swelling, ulceration etc.) and cosmetics (visible varices). The first management of CVI includes conservative measures to decrease the symptoms and prevent the progression of the disease. Specific treatment is planned based on the severity of the disease determined according to the CEAP classes. In cases where conservative and pharmacologic treatment fail, interventional management is initiated. It has been recommended to meet three main objectives when planning surgical treatment, for CVI: (1) permanent removal of varicosity together with the source of venous hypertension, (2) to obtain a cosmetic outcome as much as possible, and (3) to minimize the number of potential complications [7].

Surgical treatment methods such as stripping and high ligation of the Saphenous vein (SV) have been the leading therapeutic options for a long time and still remain an important option. On the other hand, endovenous treatment methods (both thermal and non-thermal techniques) in the treatment of CVI have gained increasing popularity worldwide. Among these endovenous techniques, percutaneous embolization of SV with n-butyl cyanoacrylate (NBCA) is a relatively new, non-thermal, and non-tumescent method, and has become the most preferred and safest methods with great early and middle-term outcomes. The use of NBCA glue in cerebral aneurysms and arteriovenous malformation has been approved by the US Food and Drug Administration (FDA) [8]. This agent is also used in the treatment of venous dilatations such as varicose and mesenteric varices [9]. However, long term outcomes with this technique have not been widely studied, and thus there are still some concerns about long-term recurrences.

The objective of this study was to present the preliminary results of a combination of percutaneous embolization of SV with NBCA and high ligation, which is a novel modified method that we have developed.

Materials and Methods

Patients and Study Design

In this study, patients who presented to our hospital between January 2018 and December 2018 due to the complaints of dull pain, heaviness or feeling leg pressure, swelling, fatigue, nighttime cramps, and itching or burning in legs were evaluated. Patients with deep vein thrombosis (DVT), hypertension, thrombophilia, severe coronary heart disease, chronic obstructive pulmonary disease, heart failure, and active ulcers were excluded from the study. A total of 47 patients, aged between 28 and 62 years, and diagnosed with chronic venous insufficiency were included in the study. The patients were evaluated with the Comprehensive Classification System for Chronic Venous Disorders (CEAP), and Venous Clinical Severity Score (VCSS). Patients' demographic features such as age and gender, and clinical features such as CEAP classes, VCSSs, and vena saphena magna VSM diameters were recorded. Patients underwent pre- and postoperative duplex ultrasonography as standing in order to access the status of the greater saphenous vein and the saphenofemoral junction. In this examination, the presence of reflux was investigated, reflux time, and diameters of VSM were measured. A reflux flow time > 0.5 s at the saphenofemoral junction was accepted as a pathological condition, and all of our patients had incompetent saphenofemoral junction.

After the beginning of the study, the necessary approval was obtained from the local ethics committee and the written and verbal procedural consents were taken from all patients. The study was conducted in line with the principles of the declaration of Helsinki.

CEAP Evaluation

CEAP classification, which was developed for the first time in an international consensus conference held in 1994, is based on the evaluation of clinical manifestation, etiological factors, anatomic distribution of the disease, and underlying pathophysiological findings. CEAP classification system involves three major components as the number of affected anatomical segments, degree of the sign and symptoms, and disability [5] (Table 1).

Table 1 CEAP classification

CEAP classification-C section	
C0	There is no sign of venous disease in the leg
C1	The person has spider or reticular veins
C2	Varicose veins are present
C3	Edema (swelling) of the ankle, best visualized from the back rather than the front
C4 a, b	Pigmentation (darkening) of the skin, eczema (redness, itching), lipodermatosclerosis (hardening of the soft tissues), and atrophie blanche
C5	A healed venous ulcer is present
C6	An active open venous ulcer is seen on the skin

Venous Clinical Severity Score

VCSS is a scoring system consisting of nine items each of which is scored with a severity scale between 0 and 3 points. These items include pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, and active ulcers (number, duration, and diameter). VCSS facilitates follow-up of the disease features, changing with the treatment. VCSS were pre- and postoperatively measured and evaluated in all patients.

Procedural Approach

All patients were treated with a novel modified hybrid technique including Venablock embolization system (Invamed RD, Ankara, Turkey) and surgical high ligation of the greater SV. In addition, patients' preprocedural, intraprocedural, and postprocedural period follow-up data were recorded and retrospectively analyzed. All hybrid procedures were performed by experienced surgeons. Before the procedure, the necessary marking for high ligation of SV was done on the skin. Following local anesthesia, high ligation of the greater SV including all lateral branches in the saphenofemoral junction was performed through an approximately 2–3 cm long incision in the groin. Ultrasound-guided NBCA embolization of the greater SV was then performed through a percutaneous puncture at the level of the medial knee. After providing appropriate antisepsis of the leg, the saphenous vein was cannulated by the guidance of US at the access site. The catheter was then inserted 3 cm behind the saphenofemoral junction. After the delivery system was prepared, NBCA was put in the injector, and a microcatheter was placed at the end of the injector. The end of the microcatheter was placed 3 cm below the saphenofemoral junction. The position of the microcatheter was confirmed by ultrasound, and external compression was applied at proximal of the vein with an ultrasound probe, and the solution was delivered into the vein. The gun trigger was compressed for 5 s, and the catheter was pulled back continuously and simultaneously as 2 cm/s. The procedure was repeated until all vein segments were occluded. All veins were controlled with ultrasonography after the procedure. The success of the procedure was defined as the feasibility and completion of the procedure without any technical problems. Because, several factors such as cannulation failure of the greater SV, failure to reach the saphenofemoral junction during catheter progression due to the tortuous course of the vessel, and inadequate occlusion of all vein segments can technically lead to failure of the procedure. All patients were uneventfully discharged 2–3 h after the procedure and were evaluated again with physical examination and duplex ultrasonography 10 to 14 days after the procedure.

Statistical Analysis

Statistical analysis was performed by "IBM SPSS Statistics for Windows, Version…" (Armonk, NY, IBM Corp.) software. The continuous variables were expressed by mean ± standard deviation, and categorical data by frequency (n) and percentage (%). Nominal variables were compared with each other utilizing chi-square and the Fisher exact tests. A p value < 0.05 was considered as statistically significant.

Results

Clinical profiles of the patients are summarized in Table 2. The mean age of the patients was 42.2 ± 8.9 (range 28–62) years. Of all patients, 22 (46.8%) were females and 25 (53.2%) were males. The mean age was found as 44.7 ± 8.98 (range 31–57) years in female and 40.0 ± 8.9 (range 28–62) years in male patients. Reflux duration measured with a duplex scan was prolonged (> 4 s) in 44 (93.6%) patients. Reflux duration was measured between 1 and 4 s in the remaining patients.

According to the CEAP classification, 38 patients (80.8%) were classified as C3, six patients (12.8%) as C4, and three patients (6.4%) as C2. CEAP class was C3 in majority (38/47) of the patients, with 22 (46.8%) female and 22 (53.2%) male patients in C3 class.

Table 2 Clinical profiles of the patients

Variables	*n*	%
Gender		
Male	25	53.2
Female	22	46.8
Reflux duration		
1–4 s	3	6.4
> 4 s	44	93.6
CEAP classification		
C2	3	6.4
C3	38	80.8
C4	6	12.8
Preoperative VCSS		
11	6	12.8
10	9	19.1
9	13	27.7
8	9	19.1
7	10	21.3
Postoperative VCSS		
2	16	34.0
3	22	46.8
4	9	19.1

CEAP, clinical, etiological, anatomical, and pathophysiological; *VCSS*, Venous Clinical Severity Score

The mean preoperative VCSS of the patients was calculated as 8.83 ± 1.31 and the mean postoperative VCSS was calculated as 2.85 ± 0.71 (range 7–11). The highest VCSS was found as 11 in 6 patients (12.8%), followed by 10 in 9 (19.1%) patients, 9 in 13 (27.7%) patients, 8 in 9 (19.1%) patients, and 7 in 10 (21.3%) patients.

The mean VCSS was significantly improved in all patients in the control visits compared with that in the preoperative values. The mean postoperative VCSS was calculated as 2.85 ± 0.71 (range 2–4). The postoperative VCSSs were found as 2 in 16 (34.0%) patients, 3 in 22 (46.8%) patients, and 4 in 9 (19.1%) patients. The mean postoperative VCSS was statistically significantly lower than the mean preoperative VCSS ($p < 0.05$).

The mean operation time was 48.2 ± 10.7 (range 25–65) minutes. Control Doppler ultrasonography was performed in all patients 10 to 14 days after the procedure. None of the patients developed postoperative complications or side effects such as phlebitis, infection, and DVT. The greater SV was completely occluded in all patients. Accordingly, the technical success rate of the new modified hybrid method was found as 100%.

Discussion

Surgical options are performed in chronic venous insufficiency (CVI) when conservative treatments fail. In addition, there are studies reporting that surgical treatment is superior over the conservative therapies in the treatment of CVI [10]. Improved quality of life with CVI surgery has been shown to be statistically significant [11]. Surgery has been the gold standard for long years for the treatment of superficial venous incompetence. Among these surgical techniques, high ligation with or without stripping, phlebectomy, ambulatory selective varice ablation under local anesthesia (ASVAL), and powered phlebectomy (TIPP) are the leading methods. Sclerotherapy, ligation, and even stripping used to control saphenous reflux are morbid procedures because recurrence rates are high due to the neovascularization of saphenofemoral junction [12].

On the other hand, endovenous treatment methods have gained increasing popularity worldwide in the treatment of CVI due to their less invasive nature. Today endovenous treatment under anesthesia is recognized as an internationally recognized standard for venous practice. The rate of complications is low with these techniques, and the use of ultrasound-guided tumescent has increased the effectiveness. However, the use of a tumescent prolongs the procedural time.

New techniques such as radiofrequency or laser ablation, endovenous thermal ablation (EVTA) and ultrasound-guided foam sclerotherapy (UGFS) are increasingly adopted within the last decade [13]. However, studies are needed to compare the long-term outcomes of these innovative methods [14]. Among these endovenous techniques, percutaneous embolization of the greater SV with NBCA is a novel method with satisfying short- and middle-term results. This procedure was described for the first time by Almeida et al. and the occlusion rate was reported as 92% in 38 patients after 2 years [15]. The success rates of this procedure have been reported between 80.1 and 100% in various studies [16, 17]. However, long-term outcomes with this technique have not been widely studied, and thus there are still some concerns about long-term recurrences. The advantages and disadvantages of the endovenous techniques (laser, radiofrequency, sclerotherapy, and NBCA) are presented in Table 3.

High ligation and stripping of GSV also are among the most common methods for the treatment of CVI [18]. However, this method has some disadvantages such as a high number of incisions and longer operation time. In recent years, studies have focused on the elimination of disadvantages by new hybrid methods that combine above mentioned different surgical methods. Based on this point, in the present study, we developed a novel method combining percutaneous embolization of SV with high ligation. The advantages of this technique are prevention of the use of heat and elimination of tumescent anesthesia. In addition, the need for epidural and subdural anesthesia is avoided and only local anesthetic to the catheter site is sufficient with this technique. In high ligation of SV, all branches are not adhered to, leading to potential recurrences. Furthermore, operation time is longer with this technique. In our method, both branches of GSV are adhered to, and operation time is shortened, thus decreasing

Table 3 Advantages and disadvantages of the endovenous techniques

	Advantages	Disadvantages
Laser	*Better in a very large diameter vein *Minimal recovery time *Eliminating needle phobia *Less discomfort *Long-lasting results *No need for stockings	*More bruising *Risk of skin burns *Feelings of burning and pain *Risk of infection *Changes in skin color
Radiofrequency	*Less bruising *Lower risk of perforation *Less post-op pain *Minimal recovery time *Higher QoL parameters *Greater patient satisfaction	*Need to contact the vein wall *Need for experienced professionals *Pins and needles sensation *Bleeding
Sclerotherapy	*Being a simple procedure *No hospitalization required *Resuming normal daily activities in a short time *More effective in spider veins	*Need for re-injections *Discomfort side effect *Burning sensation immediately after the injection *Need for compression stocking *Potential allergic reactions
N-butyl cyanoacrylate	*Free of needle-stick injury *Rapidly applicable *Easy to use *Excellent bacteriostatic activity *Decreased repair time *Good cosmetic outcome	*Reduced tensile strength *Cannot be used in insulin-dependent patients

the possibility of infections. In fact, the mean operation time in our study was found as 48.2 min. This time was reported as 61.87 min in a study using GSV ligation combined with foam sclerotherapy. In the same study, this duration was found as 89.81 minuted with conventional surgery [19]. Again in a study using a combination of endovenous laser ablation and ultrasound-guided high ligation, the mean operation time was found as 63.7 min [20].

Deep vein thrombosis has been reported in 0.4%–5.7% of the cases following stripping with high ligation [21]. Again in another study rate of infection was reported as 13.7% following high ligation of GSV alone [22]. In our study, none of the patients developed deep vein thrombosis, phlebitis, or infection. In a multi-center randomized controlled study, the occlusion rate was reported as 99% for NBCA and 96% for radiofrequency ablation [23]. The recently published results of thermal ablation have reported occlusion rates between 95 and 97% [24, 25]. In the present study, the closure rate was found as 100% in the postoperative controls. However, as this is a preliminary study, these results are short term, and longer term outcomes are needed. None of our patients developed partial occlusion or recanalization.

Color Doppler–guided perforator vein sealing has gained popularity as an effective method in the treatment of perforator vein insufficiency. This procedure can be performed with athermal methods such as sclerotherapy and cyanoacrylate glue. However, color Doppler–guided leaking vein obliteration with foam sclerotherapy has a risk of systemic embolization with every injection [26]. Furthermore, the success rate for treatment of great saphenous vein with Doppler-guided foam therapy was reported as 75% with frequently needed repetitive treatments [27]. Color Doppler–guided vein embolization using cyanoacrylate glue is a relatively newer method developed to overcome the disadvantages of foam sclerotherapy. This technique requires no assistants and enables the physician to keep watching the injection site while listening to Doppler sounds of injection and aspiration [28].

Study Limitations

Our study is a pilot study with a small number of patients and short follow-up duration.

Conclusion

In this study, in which a combination of NBCA, which is among the new methods for the treatment of CVI, and high ligation of GSV was used, the technical success rate was found as 100%. We believe that this novel method is efficient and safe in the treatment of chronic venous insufficiency, because it eliminates the need for general anesthesia with short operation time and adhesion of all branches of the saphenous vein, thus preventing possible complications. However, our results should be supported by further randomized controlled studies with a larger series of patients, in comparison with the other techniques.

Authors' Contributions ERU: conceptualization, study design, project writing and management, defining the study, extensive literature search, practical work, operative work, data acquisition, data analysis, statistical inferences, manuscript writing, and repeated editing and reviewing of the manuscript.

UTKK: Conceptualization, study design, project writing and management, defining the study, extensive literature search, practical work, operative work, data acquisition, data analysis, statistical inferences, manuscript writing, and repeated editing and reviewing the manuscript.

AY: conceptualization, study design, project writing and management, defining the study, practical work, operative work, data analysis, manuscript writing, and repeated editing and reviewing the manuscript.

YV: Practical work, operative work, data analysis, and reviewing the manuscript.

OU: Practical work, operative work, data acquisition, and reviewing the manuscript.

KE: Practical work, operative work, data analysis, and reviewing the manuscript.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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