

# Effectiveness of internal compression therapy in primary safen vein failure

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## ABSTRACT

**Aim:** The aim of this study is to evaluate the effectiveness of internal compression therapy (ICT), a new technique used in the treatment of chronic venous insufficiency (CVI), and to share the early results.

**Material and Method:** Between September 2018 and June 2019, 27 patients with superficial venous insufficiency due to saphenofemoral junction (SFJ) insufficiency and who underwent ICT were included in the study. Demographic data, venous color doppler ultrasonography (RDUS) results, CEAP (clinical etiology, anatomy, pathophysiology) classification, venous clinical severity score (VCSS) and visual analog scale (VAS) results were retrospectively analyzed from the files of the patients.

**Results:** It was determined that 14 of the 27 patients were female and 13 were male in the study. While the mean CEAP classification scores were  $3.9 \pm 0.5$  before the procedure, it was  $2.3 \pm 0.7$  at the 3<sup>rd</sup> month after the procedure ( $p < 0.001$ ). While the mean duration of venous reflux before the procedure was  $4.7 \pm 0.3$  seconds, pathological reflux was detected in 2 patients at the 3<sup>rd</sup> month after the procedure ( $p < 0.001$ ). While the mean VCSS score was  $11.2 \pm 3.3$  before the procedure, it was  $5.4 \pm 1.2$  at 3 months ( $p < 0.001$ ). While the mean VAS score was  $6.5 \pm 1.3$  preoperatively, the mean VAS score was  $2.7 \pm 1.4$  at 3 months after the procedure ( $p < 0.001$ ). No complications were observed in any of the patients.

**Conclusion:** We think that ICT can be used as an alternative treatment method in the treatment of superficial venous insufficiency due to valve dysfunction in SFJ.

**Keywords:** Vena saphenous magna, venous insufficiency, internal compression therapy

## INTRODUCTION

Lower extremity chronic venous insufficiency (CVI) and varicose veins are an important health problem that is very common in the population, impairs quality of life and can lead to serious complications (1,2). CVI, which affects a significant part of the society, has been found to be between 20-40% in many studies (3).

Although CVI is most commonly seen as superficial venous insufficiency, it may occur as deep venous insufficiency or perforating venous insufficiency, or in some cases, it may appear as combinations of these insufficiency (4).

CVI clinic has a very broad spectrum according to the underlying factors. It may appear as a cosmetic problem in the form of telangiectasia, or it may cause serious skin changes such as ulcers (5). The main symptoms are pain, swelling, night cramps, warmth and burning sensation, tiredness, restlessness, itching and tingling (6). The basic pathology constituting CVI is an increase

in venous pressure, that is, venous hypertension (7). This hypertension consists of insufficiency of the valves in the veins, occlusion in the veins or a combination of these (8).

Most treatment strategies are more conservative. Methods such as compression stockings, exercises and venoactive drugs are used in the treatment. However, these treatments cannot provide adequate or long-term protection in patients. The purpose of the treatment of CVI is the elimination of reflux (9). For many years, only ligation and external valvuloplasty (EVP) could be performed in the vena saphenous magna (VSM), especially in reflux at the level of SFJ, and surgical methods such as stripping were applied to the VSM as standard treatment. However, in recent years, endovenous interventions such as laser ablation (EVLA), radiofrequency ablation (RFA) and n-butyl cyanoacrylate embolization have found widespread use (10).

One of these methods is ICT, which is a newly developed technology and can be applied percutaneously interventionally. In this method, a mixture of hyaluronic acid and n-butyl-cyanoacrylate (n-BCA) is placed in the form of a gel implant around the insufficiency deep venous and/or SFJ terminal valve and between the fascia, which is a rigid support tissue. The procedure is also called percutaneous valvuloplasty. Thus, coaptation of the valves is achieved by reducing the circumference of the vessel with an exoskeleton formed with a non-absorbable biopolymer around the vessel wall, thus bringing the valves closer to each other (11,12). The use of ICT, which is a percutaneously applied valvuloplasty technique, instead of traditional surgical treatments in significant saphenofemoral insufficiency, and the preservation of VSM for grafts that may be needed in future cardiovascular surgeries are seen as one of the important advantages of ICT (13,14).

In this study, we aimed to share our short-term experience and results in our clinic of the ICT method, which has been used recently as an alternative to classical surgical and endovascular treatment methods in the treatment of superficial venous insufficiency of VSM.

## MATERIAL AND METHOD

In this study, the files of all patients who had valvular leakage at the SFJ and underwent ICT for primary saphenous vein insufficiency between September 2018 and June 2019 in the Department of Cardiovascular Surgery of Kırıkkale University Medical Faculty Hospital were retrospectively reviewed. The study was conducted in accordance with the principles stated in the Declaration of Helsinki. This study was carried out with the permission of Kırıkkale University Faculty of Medicine Non-Invasive Scientific Research Ethics Committee (Date: 29.04.2021, Decision no: 2021.04.17).

All patients signed the informed consent form before the procedure. The files of the patients who had a reflux time of 4 seconds or more on CDUS, had a VSM diameter of less than 5.5 mm, were diagnosed with primary saphenous vein insufficiency and underwent ICT were reviewed. A total of 27 patients were included in the study, except for those who lacked data in their files and did not give permission to work in their consent.

Patients with post-thrombotic or congenital superficial venous disease, previous intervention for venous insufficiency, and deep thrombosis were not treated. Again, no intervention was performed in those with any deep and perforating vein insufficiency.

The demographic characteristics of the patients, the reflux in the SFJ and the diameter of the VSM in the

preoperative and postoperative 3rd month RDUS results were examined.

Demographic characteristics, preoperative and postoperative 3rd month CDUS results were recorded from the files of the patients. The venous system was evaluated with CDUS, and the location and duration of reflux and the diameter of the VSM were evaluated. Reflux of 0.5 seconds or more in superficial veins, deep femoral veins, and deep calf veins is considered pathological. Reflux of 0.35 seconds or more in perforating veins is considered pathological. (15,16). In the study, CDUS examinations of the patients were evaluated based on the reports made by the Radiology Clinic. (13-5 and 9-4 MHz multifrequency linear probe, Acuson Antares, Siemens Medical Solutions USA, Inc. instrument)

The CEAP, VCSS and VAS data we used in the follow-up were evaluated before and after the procedure at 3 months. Complications that may develop during and after the procedure (bleeding, infection, ecchymosis, pigmentation, phlebitis or deep vein thrombosis) and the duration of the ICT procedure were recorded.

### CEAP Classification

CEAP classification was used for the diagnosis and evaluation of CVI by considering all the findings. In CEAP classification, C: represents clinical appearance, E:etiological factors, A:anatomical distribution, P:pathophysiological status (17).

### VAS

VAS scoring was used to determine the severity of symptoms. It is applied by asking patients to rate their pain intensity on a 10-unit scale, with a value of "0" indicating that they have no complaints, and a value of "10" indicating that their complaints are very severe (18).

### VCSS

VCSS system, which is based on scoring up to 3, was used to evaluate the treatment efficacy of venous disease. In VCSS system, patients of clinical complaints, findings (pain, varicose veins, edema, skin pigmentation, inflammation, induration, active ulcer number, active ulcer duration, active ulcer diameter) and previous conservative treatments (compression stocking use and elevation) are evaluated (19).

### Process

The procedure was performed in the operating room under local anesthesia and with the help of RDUS. A mixture of hyaluronic acid vial and n-butyl-cyanoacrylate vial (RD Global-Invamed, Ankara, Turkey) was formed and an average of 2.1 cc polymer was injected with 19 G needles around the VSM valves at SFJ. After it was seen that adequate coaptation was achieved, the procedure was terminated. The treated extremity was put on an

elastic bandage for compression, and the bandage was removed 48 hours later. All patients were discharged on the same day.

**Statistical Analysis**

The analysis of the data used in the study was performed using the SPSS for Windows 21.0 package program (SPSS Inc. Chicago, IL, USA). Categorical variables were expressed as percentage (%), continuous variables as mean±standard deviation (mean±std). The Kolmogorov-Smirnov test was used to evaluate the normal distribution of the data used in the study. Student’s t-test was used to compare numerical variables. The chi square test was used to compare categorical variables. A P value less than 0.05 was considered statistically significant.

**RESULTS**

Of the 27 patients, 14 were female and 13 were male. The mean age was 45.7±8.3 (35-59) years. The mean procedure time was 17±3 minutes.

While the reflux time was 4.7±0.3 seconds before the procedure, it was 0.4±0.1 seconds at the 3rd month after the procedure. Pathological reflux was detected in a total of 2 (7.4%) patients. This result was statistically significant (p<0.001). The data are shown in **Table 1**.

	<b>Preoperative (n=27) mean±std</b>	<b>Postoperative (n=27) mean±std</b>	<b>P</b>
Reflux time (s)	4.7±0.3	0.4±0.1	<0.001

SFJ: Safenofemoral junction, std: Standard deviation

While the mean CEAP classification scores of the patients were 3.9±0.5 before the procedure, it was 2.3±0.7 at the 3rd month after the procedure. While the mean VCSS values were 11.2±3.3 before the procedure, it was found to be 5.4±1.2 at the 3rd month after the operation. While the mean VAS score was 6.5±1.3 before the procedure, the mean VAS score was 2.7±1.4 3 months after the procedure. These results are statistically significant (p<0.001). The data are shown in **Table 2**.

	<b>Preoperative (n=27) mean±std</b>	<b>Postoperative (n=27) mean±std</b>	<b>P</b>
CEAP	3.9±0.5	2.3±0.7	<0.001
VCSS	11.2±3.3	5.4±1.2	<0.001
VAS	6.5±1.9	2.7±1.4	<0.001

CEAP: Clinical etiology, anatomy, pathophysiology, VCSS: Venous clinical severity score, VAS: Visual analog scale, std: Standard deviation

Bleeding, infection, ecchymosis, pigmentation, phlebitis or deep vein thrombosis were not observed in any of the patients after the procedure. In addition, no significant change was detected in the mean VSM diameters.

**DISCUSSION**

In our study, in which we evaluated the results of the ICT method in patients with chronic superficial venous insufficiency, a significant improvement was found in CEAP classification, VAS and VCSS scores by evaluating the data we obtained at the end of the 3-month follow-up. These results show us that the ICT method stands out as an alternative treatment to other methods in which VSM is preserved in venous insufficiency due to SFJ reflux.

In recent years, minimal incisions and/or percutaneous pathological venous structures can be treated even with local or tumescence anesthesia, but the VSM structure cannot be preserved in these methods (occlusion, obliteration, striping). This may cause problems in the future when VSM is required to be used as a graft (20). This leads to the search for new treatments. One of these is EVP, a reconstructive surgery method that reduces the diameter of the VSM by using different materials (dacron, PTFE) from the outside to correct the coaptation of the valves in the SFJ (21). A new procedure, ICT, uses a polymer composed of cyanoacrylate and hyaluronic acid, developed according to the effects of compression materials. This polymer is injected percutaneously around the femoral and/or SFJ under RDUS guidance. In this way, the diameter of the vessel is reduced and the function of the valve with insufficiency is restored. This procedure is also called percutaneous valvuloplasty (22).

Although the application of this EVP procedure has increased recently (15%), studies are still scarce, and when the literature is examined, it is reported that different results are obtained in interventions performed on patients with primary saphenous vein insufficiency (23). In a study conducted by Saraç et al. ( 24) on 83 patients with isolated saphenous vein insufficiency, they reported that in the results of two year surgical EVP, symptomatic improvement was detected in 51 (61.4%) patients, and additional procedures were performed in the remaining 32 patients. In addition, Muhlberger et al. (25) EVP in their study of 210 patients; reported that the procedure was effective in 95.24% of the patients and the VCSS decreased from 4.76 preoperatively to 1.77 6 months after the operation. The findings in this study are similar to our study. Although the procedures in these studies are similar in mechanism, they are performed with surgical intervention. It is a more invasive method compared to ICT.

Complications such as infection, bleeding, hematoma, venous stenosis, deep vein thrombosis, thrombophlebitis and reoperation can be seen after the EVP procedure (26). In their ten years study, Joh et al.

(27) reported the diffuse thrombosis rate of VSM as 12.9%. In addition to these studies, Günaydın et al. (28) performed percutaneous valvuloplasty in 44 patients with primary VSM failure. There were no complications in any patient, venous reflux completely disappeared in 37 (84%) patients in their four month follow-up, mild reflux in 2 (4.5%) patients, 1 (2.2%) reported that moderate reflux was observed in the patient. Our results show parallelism to this study and only 2 (7.4%) patients had pathological reflux. In addition, no complications were observed in our study, and we attribute this result to the fact that it is a less invasive procedure performed with CDUS.

Due to the lack of CEAP classification in detecting post-treatment changes, evaluating response to treatment, and comparing the efficacy of different treatment modalities, scoring systems related to clinical severity of the disease were needed. The VCSS system, which evaluates the clinical complaints and findings of patients and their conservative treatments due to CVI, is used to evaluate the treatment effectiveness of venous disease (29). Eroğlu and Acıpayam (30), in their study on 12 patients who underwent ICT due to primary superficial venous insufficiency, showed that the CEAP classification was CEAP 2 (1-4) before the procedure, while it was CEAP 3 (3-4) in the follow-up one month later. They also reported that the VCSS was 6 at the follow-up one month later, while the VCSS score was 10 before the procedure. In our study, we also obtained similar results in terms of reflux time, CEAP classification and VCSS scoring.

Pain in CVI is one of the most common symptoms that negatively affects the work and social life of the person by impairing the quality of life (31). After CVI treatment, VAS, which is a practical evaluation method, can be used in the evaluation of pain to quantify some values that cannot be measured numerically in deciding the effectiveness of the treatment (32). In our study, the mean VAS score was  $6.51 \pm 1.3$  before the procedure, while the mean VAS score was  $2.36 \pm 1.34$  6 months after the procedure. This result is consistent with the literature as an indication that the ICT method improves the quality of life in patients (33).

We think that the ICT procedure is a fast and effective method in the treatment of patients with chronic venous insufficiency due to saphenofemoral junction valve insufficiency, and that it can be applied under day care conditions has an important advantage over other methods.

The limitation of this study is that it is retrospective and single-centered. Studies with a larger patient population and longer follow-up are needed.

## CONCLUSION

In this study, it has been shown that ICT is a fast and effective percutaneous treatment method and improves the patient's clinic in a short time that can be used in superficial venous insufficiency, which reduces and eliminates venous reflux in SFJ by preserving VSM.

## ETHICAL DECLARATIONS

**Ethics Committee Approval:** This study was carried out with the permission of Kırıkkale University Faculty of Medicine Non-Invasive Scientific Research Ethics Committee (Date: 29.04.2021, Decision No: 2021.04.17).

**Informed Consent:** All patients signed the free and informed consent form.

**Referee Evaluation Process:** Externally peer-reviewed.

**Conflict of Interest Statement:** The authors have no conflicts of interest to declare.

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**Author Contributions:** All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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