



# Thermal ablation, nonthermal ablation and surgical stripping applications: 1-year single center early results

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## Abstract

### *Thermal ablation, nonthermal ablation and surgical stripping applications: 1-year single center early results*

**Objective:** Starting from the 1990's minimally invasive methods such as endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and ultrasound-guided foam sclerotherapy (UGFS) developed.

**Method:** This study includes a total of 136 patients (81 women/55 men), of whom 22 (10 women/12 men) were treated with classic surgical stripping, 54 (32 women/22 men) with thermal ablation and 60 (39 women/21 men) with non-thermal ablation.

**Results:** Twenty-two patients (10 women/12 men) were treated with surgical stripping. In one female patient a hematoma arose in the medial crural region postoperatively. A radiofrequency catheter (ThermoBLOCK TM) was used in the thermal ablation procedures in 54 patients (32 female/22 male). While permanent paresthesia occurred in one female patient after the procedure, temporary paresthesia occurred in 3 male patients postoperatively. Non-thermal ablation was performed in 60 patients (39 female/21 male). Even through a severe burning sensation was present in 6 patients (5 female/1 male) during the procedure, this symptom was only transient. In one of the patients, deep venous thrombosis (DVT) occurred at the level of the popliteal vein postoperatively at the sixth day.

**Conclusion:** Even if thermal and non-thermal ablation and surgical procedures have the same pain decreasing rates, hematomas and a longer hospital stay are more frequent in surgical procedures.

**Keywords:** Venous Insufficiency, Stripping, Thermal Ablation, Non-Thermal Ablation

## Öz

### *Termal ablasyon, nontermal ablasyon ve cerrahi stripping uygulamaları: 1 yıllık tek merkezde erken sonuçlar*

**Amaç:** 1990'lı yıllardan başlayarak endovenöz lazer ablasyon (EVLA), radyofrekans ablasyon (RFA) ve ultrason eşliğinde köpük skleroterapi (UGFS) gibi minimal invaziv yöntemler geliştirildi.

**Yöntem:** Bu çalışma toplam 136 hastayı içermektedir (81 kadın/55 erkek) 22' (10 kadın/12 erkek) klasik cerrahi stripping, 54' (32 kadın/22 erkek) termal ablasyon ve 60' (39 kadın/21 erkek) termal olmayan ablasyon ile tedavi edildi.

**Bulgular:** Yirmi iki hasta (10 kadın/12 erkek) cerrahi stripping ile tedavi edildi. Bir kadın hastada operasyon sonrasında kruris medialinde hematoma meydana geldi. 54 hastada (32 kadın/22 erkek) termal ablasyon işlemlerinde radyofrekans kateter (ThermoBLOCK TM) kullanıldı. Bir kadın hastada işlem sonrası kalıcı parestezi gelişti. 3 erkek hastada ameliyat sonrası geçici parestezi gelişti. 60 hastaya (39 kadın/21 erkek) termal olmayan ablasyon uygulandı. 6 hastada (5 kadın/1 erkek) işlem sırasında şiddetli yanma olmasına rağmen bu semptom geçiciydi. Bir hastada postoperatif altıncı günde popliteal ven düzeyinde derin ven trombozu (DVT) gelişti.

**Sonuç:** Termal ve termal olmayan ablasyon ve cerrahi işlemler aynı ağrı azaltma oranlarına sahip olsa da cerrahi işlemlerde hematomlar ve hastanede daha uzun süre kalış daha sık görülür.

**Anahtar Kelimeler:** Kronik Venöz Yetmezlik, Stripping, Termal Ablasyon, Termal Olmayan Ablasyon

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## INTRODUCTION

The lower extremity venous system consists of the superficial, perforating and deep venous vessels (1). Lower extremity varicose veins are defined as dilated subcutaneous veins with a diameter more than 3 mm (2). Superficial or perforating venous insufficiency is described as a reverse backflow of more than 500 milliseconds, in a standing position when applying distal compression (3). Approximately, one-third of the World population is affected by chronic venous insufficiency in the lower extremities (4).

Pain is the most common symptom in patients with chronic venous insufficiency, but in some untreated patient groups, chronic venous insufficiency causes ulcers that are triggered by chronic inflammation and are difficult to treat (6).

Varicose veins originating from reflux at the saphenofemoral junction, can be managed with a small incision, called stripping. In this traditional surgical procedure, the saphenous vein departing from the saphenofemoral junction is excised (7). Even though this surgical method is the gold standard, complications such as bleeding, nerve damage and recurrence is 5 percent (8).

Starting from the 1990's minimally invasive methods such as endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and ultrasound-guided foam sclerotherapy (UGFS) developed. In non-thermal methods, the affected vessel is injected with a sclerotizing agent which turns into foam. This is done with the aid of a doppler ultrasonic probe (10). The irritating feature causes the endothelial and subendothelial layers of the vessel to be inflamed, which leads to fibrosis and the vessel to be clogged (11).

The most frequently used thermal ablation technique, radiofrequency ablation is performed by injecting tumescence liquids above the affected vessel under local anesthesia. If the patient and surgeon prefer, it can also be done under spinal anesthesia (12).

Thermal and non-thermal ablation methods have less bleeding, infection and nerve damage risk, and require shorter hospitalization, that's why they are more frequently used recently (13,14).

In this research we wanted to show, the early 3 month results postoperatively in patients that got treated with surgical stripping, thermal and non-thermal ablation due to chronic venous insufficiency.

## METHOD

Between October 2020 and October 2021, patients that got diagnosed with chronic venous insufficiency, were included in this study and studied retrospectively. This study includes a total of 136 patients (81 women/55 men), of whom 22 (10

women/12 men) were treated with classic surgical stripping, 54 (32 women/22 men) with thermal ablation and 60 (39 women/21 men) with non-thermal ablation. All of the patients were informed about the surgery and its risks, and finally signed the informed consent.

All operations were performed by the surgery team and the same anesthesiological support, at the cardiovascular department at the Hatay Mustafa Kemal University Tayfur Ata Sökmen Medical Faculty. This study was authorized by the ethics committee of Medical Faculty with the document dated 17/03/2022, meeting number 03 and decision number 11.

All patients with all pain symptoms underwent lower extremity venous doppler ultrasonography prior to the surgery. The lower superficial and deep venous vessels were examined in detail. Variations, old thrombosis, perforating veins were noted. The presence of two criteria decides whether there is need for intervention or not. The first one is the great saphenous vein having a diameter of 5,5mm or above. The second one is having a reflux of at least 0,5 seconds at this vein when performing a Valsalva maneuver.

In this study only one lower extremity intervention of all patients was included. Patients with a history of malignancy, deep vein thrombosis, thrombophlebitis, peripheral artery disease, pregnant patients, short life expectancy, severe cardiac pathology, no preoperative lower extremity pain/complaints, or active venous ulcer were excluded from the study.

In thermal and non-thermal ablation techniques, the success rate is affected when the diameter of the saphenous vein is above 12 mm patients: Patients with a diameter above 12 mm were left out of the study to prevent statistical confusion. Furthermore, patients who came the third month postoperatively were chosen. There was no statistically significant difference between the diameters of the great saphenous veins of the treated patients.

When choosing the procedure, the risks and preferences were left for the patient to choose instead of the surgeon. Patients from all age groups were included in the study in accordance with the exclusion criteria.

## Application Procedure

All patients undergoing the surgical procedure, spinal anesthesia was performed. During the procedure the patient was monitored with the following parameters: ECG, arterial blood pressure, and SpO2. The patients were provided with a large vascular access, mostly in the left upper extremity to administer 500-1000ml fluid intravenously. Firstly, the region of intervention is cleaned with antiseptic tincture of iodine. Secondly, with 2% lidocaine was infiltrated subcutaneously with a small needle between L3-4, L4-5 or L2-3 until the skin

swells a little bit. The thinnest needle as possible should be used and wait until you see the CSF coming out of the needle from the subarachnoid space. Anesthetic drugs are injected into the subarachnoid space. The effectiveness of the anesthetic drugs were tested by cold application and a cunt needle. After that the surgical procedure started.

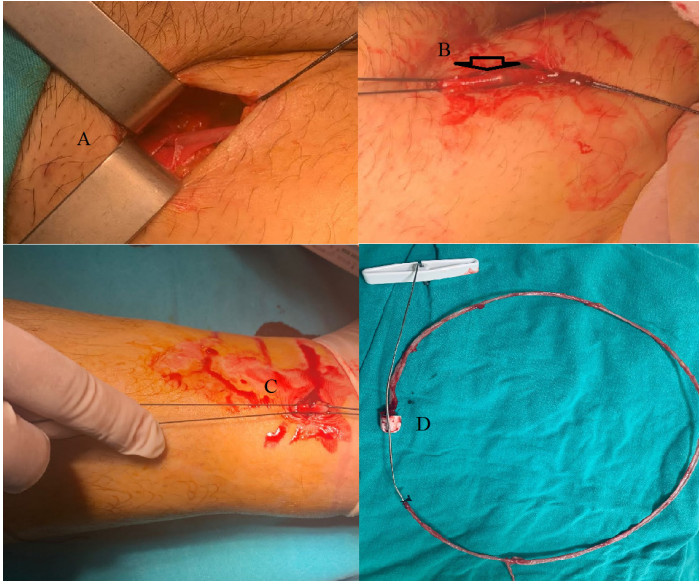


Figure 1. A: SFJ proximal saphenous vein, B: Stripper wire, C: Medial malleolus saphenous vein, D: Saphenous vein after stripping

When the great saphenous vein has a diameter of 5,5mm or above and a reflux of at least 0,5 seconds at this vein when performing a Valsalva maneuver on doppler ultrasonography, a small cut of 3 cm is made on the skin and subcutaneously, around the saphenofemoral junction. The saphenofemoral junction is found and freed from the neighboring connecting tissue and encircled with thick silk. The superficial epigastric vein and external pudendal venous structures were separated. On the anterior side of the medial malleolus a small 1 cm cut was made, and the saphenous vein was explored and encircled with thick silk. With an 11-blade scalpel an incision is made in the saphenous vein. A stripping wire was inserted and pushed proximally with the aid of a doppler ultrasonic probe. Stripping was performed and pressure was performed on the leg to prevent hematoma (Figure 1: A: SFJ proximal saphenous vein, B: Stripper wire, C: Medial malleolus saphenous vein, D: Saphenous vein after stripping).

In the presence of varicose veins, microphlebectomy was performed, and the operation finished after bleeding control (Figure 2: A varicose vein being excised with microphlebectomy).

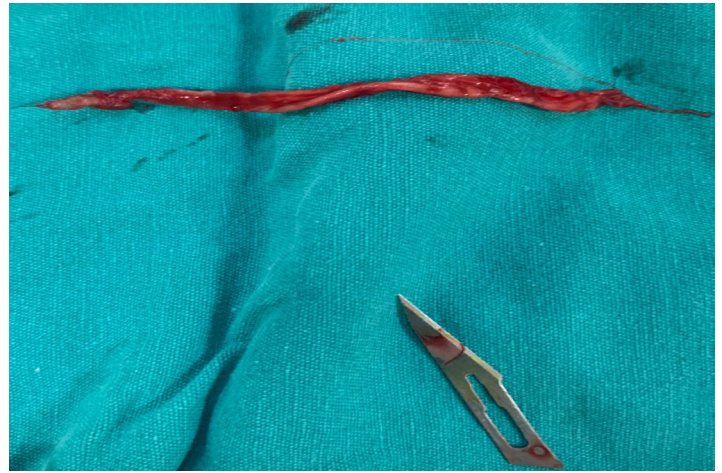


Figure 2. A varicose vein being excised with microphlebectomy

Radiofrequency ablation procedures were performed with the ThermoBLOCK™ (Invamed, Ankara, Turkey, CE 2292) system which the health insurance provides (Figure 3: Radiofrequency ablation catheter and power supply).



Figure 3. Radiofrequency ablation catheter and power supply

In addition to the informed consent of the surgical procedure, complications such as thermal nerve injuries, skin burns, deep venous thermal injuries and deep venous thrombosis were clearly explained to all patients. The procedures were performed under sedation. The saphenous vein was identified with a doppler ultrasonic probe, in a suitable below the knee position. With the aid of a guide wire, a 7-sheath catheter was inserted, the Intermittent illuminated ThermoBLOCK™ radiofrequency ablation catheter was advanced 2 cm distal to the saphenofemoral junction. After the location of the ablation catheter was assured, Tumescant anesthesia fluid prepared by the anesthesia unit was applied around the saphenous vein with the help of a Doppler USG to provide venous compression and protect the surrounding tissues from thermal injury. This tumescant solution consists of 500 mL cold isotonic solution with 40 mL sodium bicarbonate, 0.5 mg adrenaline and 5 mg bupivacaine hydrochloride added to it.

Thermal ablation energy was applied from 2 cm distal to the saphenofemoral junction. In each segment, 10 J energy was given per mm of diameter due to the physical characteristics

of the device, the energy was given twice at the same place, for 30 seconds each. The procedure was continued by withdrawing the ThermoBLOCK™ radiofrequency ablation catheter as much as the marked segment at each burning frequency. In patients with varicose veins microphlebectomy was performed, the operation ended after bleeding control.

Figure 4: Non thermal ablation procedures were performed with VenaBlok (Invamed, Ankara, Turkey), by preference of the health insurance system of Turkey. The surgical procedure and deep venous thrombosis were clearly explained to the patient, the patient signed an informed consent. With the aid of a doppler ultrasonic probe, the saphenous vein was detected below the knee. After puncture of the vein, a 7-sheath catheter was inserted with a guide wire. With a doppler ultrasonic probe the Venablok ablation catheter was pushed proximally until reaching 2cm distal to the saphenofemoral junction. After the location of the catheter was assured and putting pressure on the SFJ to prevent the sclerosing agent escaping into the femoral vein, the sclerosing agent was given into the saphenous vein with a speed of 1 mm per second. After injecting the sclerosing agent into the vein, we continued putting external pressure for 3 minutes. In patients with varicose veins microphlebectomy was performed, the operation ended after bleeding control.



Figure 4. Non thermal ablation procedures performed with VenaBlok (Invamed, Ankara, Turkey), by preference of the health insurance system of Turkey.

## Follow Up

After the procedure, it was verified with a doppler USG whether the saphenous vein was closed or not. The patients that underwent surgical stripping stayed one night at the hospital. The patients that underwent thermal and non-thermal ablation were only followed for 4-6 hours postoperatively. All of the patients' legs were wrapped up with an elastic bandage, leg elevation and a prophylactic dose of 4000IU units of factor Xa inhibitor was administered to all patients to prevent deep venous thrombosis. After the procedure all patients were told to use compression stockings for at least 3 months.

## Statistical Analysis

The data were analyzed with computer software Statistical Package for Social Sciences, SPSS 20. Descriptive statistics (absolute frequencies and percentages for categorical variables and means and standard deviation for continuous variables) were used to evaluate demographic and clinical characteristics of the population. Values are expressed as mean  $\pm$  standard deviation or frequency and percentage. For continuous variables, conformity of normal distribution and homogeneity were tested with the "Kolmogorov-Smirnov test." Categorical values were evaluated with "chi-square test," and parametric values were evaluated with "independent samples t-test." Spearman rank and Pearson correlation coefficients were used for correlation analysis. A P larger than 0.05 was considered statistically significant.

## RESULTS

After the surgical procedure all patients were followed in the hospital for 24 hours. All patients' legs were wrapped up with an elastic bandage from the plantar surface of the feet till the inguinal ligament. In one female patient a hematoma arose postoperatively at the medial cruris. A superficial tissue ultrasonography showed a hematoma of 3x4x7cm. This patient didn't get operated a second time, but she was followed for 48 hours in the hospital. In one female patient, soft tissue infection was seen near the inguinal region. (Figure 5: Soft tissue infection near the inguinal region) The patient received a 7-day antibiotherapy which included 1 gram of amoxicillin and clavulanic acid.

Although the occurrence of hematoma and infection complications in 1 patient was not statistically significant when compared with thermal and nonthermal ablations; If we look at the numerical value of these two complications, they are proportionally significant.



Figure 5: Soft tissue infection near the inguinal region

Thermal ablation was performed in 54 patients (32 female/22 male) with a radiofrequency catheter (ThermoBLOCK™). All punctures were performed with the aid of a doppler usg. Between the SFJ and puncture location, tumescent anesthesia was administered to all segments of the saphenous vein. We started to give the thermal ablation energy, 2cm distally to the SFJ. On each segment a 10-joule energy was given, this is due to the physical trait of the device, each segment was given energy 2 times for 30 seconds each. No hematoma was seen in any of the patients. In one patient paresthesia was seen postoperatively at the first follow-up. It is thought that it is permanent paresthesia because, even though the patient was prescribed vitamin b12 and piracetam 800mg daily, when consulted to the neurology department, after 3 months no change was seen. The patient was transferred to the neurology unit for further examination such as EMG. In 3 male patients paresthesia was noted at the first follow up. When consulted to the neurology department, vitamin b12 and piracetam 800mg daily was prescribed. At the third month none of the 3 patients described paresthesia.

Infection was not seen in any of the patients. None of the patients stayed in the hospital longer than 6 hours. After thermal ablation in 4 patients (7.4 percent) of the patients paresthesia was seen, in contrast to the 5% noted in literature.

Non thermal ablation was performed in 60 patients (39 female/21 male). With the aid of a doppler, 5ml of lidocaine was injected. The Venablok catheter was pushed until 2cm distal to the SFJ with the aid of a doppler usg. With a doppler usg probe, pressure was put on the saphenofemoral junction to prevent blood flow, and the sclerosing agent was administered with

a speed of 1 mm per second. In none of the patients hematoma occurred. During the procedure, in 6 patients (5 female/1 male) sudden severe burning sensations occurred. All patients were discharged within 6 hours after the procedure. In only one patient popliteal vein thrombosis (DVT) occurred postoperatively at the sixth day. The patient used 2x5mg of apixaban daily for 3 months. (Table 1. Application methods, sex, age, and complication numbers.). (Table 2. Mean vessel diameters and post-operative symptom)

## DISCUSSION

Chronic venous insufficiency is a health problem seen in 30 percent of the world population (15). It is known that chronic venous insufficiency affects social life and may cause serious socio-economic loss (16). Clinically, the patients suffer from swollen legs, general edema, repeating phlebitis attacks and ulcers (6). Pain was present in all of our patients; it is the most common symptom. None of the patients in this study had venous ulcers. Besides, in 92 (67.64 percent) patients, repeating lower extremity edema was a clinical finding that we came across.

Chronic venous insufficiency, which leads to so many health problems, is nowadays slowly and commonly treated with thermal and non-thermal techniques instead of surgical procedures, because of the advancements in technology (14,17). However, still in a lot of countries the surgical procedure is still the first choice (18). Secondly, it is known that patients with a saphenous vein with a diameter of 12 mm or above, thermal and non-thermal ablation techniques aren't that successful (19). Patients with a diameter of 12mm or above, were excluded from the study. It has been tried to overcome the unfair statistical results and limitation defects that may arise. The reason for this situation is that although the American Venous Surgery Association accepts radiofrequency ablation as the gold standard in terms of

**Table 1. Application methods, gender, age, number of complications.**

	Female	Male	The average age	Hematoma	Infection	Paresthesia	DVT
Surgical stripping	10	12	57.2 (± 3.7)	1	1	0	0
Thermal ablation	32	22	53.1 (± 4.9)	0	0	4	0
Nonthermal ablation	39	21	62.9 (± 7.8)	0	0	0	1

effectiveness compared to other endovenous methods, its efficacy is only in patients with a saphenous vein diameter up to 12mm.

Endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, mechanochemical ablation (Clarivein, South Jordan, UT, United States) and cyanoacrylate adhesive (VenaSeal, Medtronic, Minneapolis, MN, United States; VenaBlok, United States) have been used increasingly since the 1990s. Minimally invasive methods such as Invamed, Ankara, Turkey) have been included in the treatment protocols of cardiovascular surgeons (9,12,21).

In many studies, radiofrequency thermal versus surgical method ablation is seen as a good alternative with long-term results (22,23). Despite everything, we think that it should be compared in terms of catheter types, since the main determinant in the choice of catheter is determined by the social health insurance.

In thermal procedures hematoma is more common than in non-thermal procedure, however a more common complication is the occurrence of nerve damage due to the high heat (10). In our study, in only 1 patient hematoma arose, in 1 patient soft tissue infection occurred. If you evaluate every group on its own, you get to see a statistically significant value.

When we evaluate the recurrence of chronic venous insufficiency, some studies show recurrence percentages (24,25). We examined the disappearance of the complaints of the patients and duration of hospital stay. Pain is a symptom that vanished in all of the patients at the first month postoperatively.

#### Limitations of Study

This study has certain limitations, as the treatment is dependent on the health care social insurance providers. They only choose one brand for the radiofrequency method for thermal ablation. (ThermoBLOCK, Invamed, Ankara, Turkey). The same goes for non-thermal ablation (VenaBLOCK, Invamed, Ankara, Turkey) where again only one product is provided. In addition, the study cohort was carried out by a single operator, with a relatively small number of patients. Another limitation of the study is that it is retrospective in nature.

#### CONCLUSION

To conclude, even though surgical and non-surgical (thermal and non-thermal) procedures have the same success rate in pain management, hematoma and longer hospital stay are more frequent in surgical procedures. We believe that in the near future, the treatment plan of chronic venous insufficiency will be limited to non-surgical procedures.

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##### Peer-Review

Externally peer reviewed.

##### Conflict of Interest

The authors declare that they have no conflict of interests regarding content of this article.

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The authors report no financial support regarding content of this article.

**Table 2. Mean vessel diameters and post-operative symptom**

	Surgical stripping (n:22)		Thermal ablation (n:54)		Non-thermal ablation (n:60)		P value
Mean vessel diameter	8.9 ±1.1		8.3 ±1.7		6.8 ±1.2		0.67
Post operative VAS (same-good)	%95.45	n:21	%94.44	n:51	%90	n:54	0.61

Especially, recent studies show that thermal and non-thermal ablation techniques cause less pain, hematoma, wound infections and shorter hospital stay, and the fact that patients can return to work earlier makes these non-surgical procedures more beneficial (19,21). These procedures have more value as they decrease crowdedness and hospital stay during the Covid 19 pandemic.

### Ethical Declaration

Ethical permission was obtained from the Hatay Mustafa Kemal University, Medical Faculty Non-Clinical Research Ethics Committee for this study with date 17/03/2022 and number 15, and Helsinki Declaration rules were followed to conduct this study.

### Authorship Contributions

Concept: MOB, SU, Design: MOB, OK, SU, Supervising: MOB, İF, Financing and equipment: MOB, SU, İF, OK, Data collection and entry: MOB, SU, OK, İF, Analysis and interpretation: MOB, SU, Literature search: MO, OK, SU, Writing: UK, Critical review: MOB, SU

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