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Original Article

Long-term outcomes of radiofrequency ablation and cyanoacrylate closure for treatment of small saphenous veins

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Abstract

Aim: Superficial venous insufficiency is less prevalent in the lesser saphenous vein compared to the great saphenous vein. Treating the lesser saphenous vein often presents greater challenges due to its proximity to the sural nerve and anatomical variations. This study evaluates the long-term efficacy of radiofrequency ablation (RFA) and cyanoacrylate closure (CAC) for managing small saphenous veins and discusses our treatment approach.

Material and Methods: We performed a retrospective analysis involving 137 patients (64 treated with CAC and 73 with RFA) who received treatment for small saphenous vein insufficiency at our clinic between 2014 and 2019. We assessed quality of life and clinical outcomes at 6 months, and at 1, 3, and 5 years post-treatment.

Results: Our findings indicated that radiofrequency ablation showed greater improvements compared to cyanoacrylate embolization in terms of VCSS. However, over the 5-year follow-up period, recurrence rates were observed in 11 (17.1%) patients in the CAC group and 5 (6.8%) patients in the RFA group, with this difference being statistically significant (p=0.045).

Conclusion: Radiofrequency ablation for treating venous insufficiency offers superior long-term quality of life benefits compared to cyanoacrylate closure, particularly after three years.

Keywords: Small saphenous vein, radiofrequency ablation, cyanoacrylate adhesive

INTRODUCTION

Venous diseases, including varicose veins and chronic venous insufficiency, significantly impact public health due to their prevalence and negative effects on quality of life. Risk factors encompass age, gender, family history, obesity, and occupational standing [1]. The small saphenous vein (SSV) is a crucial component of the venous system in the lower limbs, and its insufficiency can lead to significant clinical problems.

Chronic venous insufficiency occurs when there is a disruption in normal venous blood flow. This disruption can occur in either the superficial or deep venous system or in perforating veins [2]. As a result of chronic venous insufficiency, individuals may experience symptoms such as swelling, itching, pain, as well as serious complications like hyperpigmentation, eczema and venous leg ulcers [3].

Although small saphenous vein insufficiency is less commonly suspected compared to great saphenous insufficiency due to its location on the posterior side of leg and its shorter length, approximately 20 percent of patients with symptoms of venous insufficiency are diagnosed with small saphenous insufficiency

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[4]. The treatment for small saphenous vein insufficiency is more complex than that for great saphenous insufficiency due to its relationship with sural nerve and anatomical variations [5]. The small saphenous vein runs along the posterior aspect of the calf and drains into the popliteal vein. Insufficiency in this vein typically arises due to venous valve dysfunction, leading to retrograde blood flow and venous hypertension. This condition often results from factors such as venous wall weakness, increased intraluminal pressure, or valvular incompetence. As blood pools in the vein, it can lead to symptoms such as pain, swelling, and skin changes in the lower leg. Accurate diagnosis of SSV insufficiency involves a combination of clinical evaluation and imaging techniques. Patients often present with symptoms like swelling, heaviness, and visible varicosities in the calf. Ultrasound imaging, particularly Doppler ultrasound, is the gold standard for diagnosing SSV insufficiency. This non-invasive technique allows for the visualization of venous anatomy, assessment of valve function, and measurement of blood flow. It can identify the presence of reflux, demonstrate the extent of venous dilation, and guide treatment planning. Treatment approaches for small saphenous vein insufficiency include methods such as stripping, ligation, radiofrequency ablation (RFA), laser ablation, and cyanoacrylate closure (CAC). However, research focusing on the efficacy, safety, and potential complications of these treatments specifically for small saphenous vein insufficiency is still sparse. Therefore, further investigation is warranted. In summary, small saphenous vein insufficiency is a common condition that can significantly impact patients' quality of life. Advances in diagnostic and treatment modalities have improved management options, offering less invasive and more effective interventions. Ongoing research and clinical practice will continue to enhance the understanding and treatment of this condition, aiming for better outcomes and patient satisfaction.

This study aims to retrospectively evaluate and compare the effectiveness and side effects of cyanoacrylate closure versus radiofrequency ablation in managing small saphenous vein insufficiency.

MATERIAL AND METHODS

Study Design

This independent retrospective study included a total of 137 patients (64 patients with CAC, 73 patients with RFA) treated with RFA and CAC for small saphenous insufficiency who were admitted to our clinic between 2014 and 2019. RFA and CAC treatment methods were left to the patients' preference. Informed consent was obtained from each patient before the procedure. The research adhered to the principles outlined in the Declaration of Helsinki. The study was approved by the Research Ethics Board at Ankara University (approval date: July 18, 2024; reference number: 2024/444). The patients treated for only small saphenous vein insufficiency, patients with an age range between 18 and 70 years, CEAP classification greater than 2, small saphenous vein diameter greater than 4 mm, and small saphenous vein reflux greater than 2 seconds were included in the study. Patients with deep vein thrombosis (DVT), arteriovenous malformations, old or new-onset thrombophlebitis, pregnant patients and patients who could not be followed up despite surgery were excluded.

Both treatments were performed by two separate surgeons. Procedures such as sclerotherapy and miniflebectomy were not performed. All patients were examined according to CEAP (Clinical severity, Etiology, Anatomy, Pathophysiology) classification before the procedure. Recurrence rate was evaluated by ultrasound at 6 months and 1, 2, 3 and 5 years after the procedure. Data were recorded preprocedurally and postprocedurally at 1, 3 and 5 years using the Venous Clinical Severity Score (VCSS). Patients were followed up for the presence of deep vein thrombosis, phlebitis, ecchymosis and bleeding at the intervention site. On the basis of clinical examination and electrodiagnostic test results, a sural neuropathy was obtained by neurology department. Color Doppler ultrasonography (CDUS) results were compared at each examination. Any recanalization or reflux was considered a failure.

The sample size for this study was calculated using a statistical power analysis to ensure that the results would be statistically significant and clinically relevant. The sample size was determined based on expected effect sizes, significance levels, and power, with the primary aim of detecting a difference in the recurrence rates between the two treatment groups.

Assuming an effect size of 0.5 (medium effect), a significance level (alpha) of 0.05, and a power (1-beta) of 0.80, the estimated sample size was calculated to be approximately 60 patients per group. This calculation was based on prior studies and clinical estimates of recurrence rates and complications associated with cyanoacrylate closure and radiofrequency ablation. To account for potential dropouts and missing data, the final sample size was increased to 64 patients in the CAC group and 73 patients in the RFA group, ensuring adequate statistical power and robustness of the study findings.

Device and Procedures

Both procedures were performed with patients in a prone position and under operating room conditions. Local anesthesia was used for CAC. Spinal anesthesia was used in RFA patients.

Cyanoacrylate Closure

Endovenous ablation was performed via the VariClose Vein Sealing System (Biolas, FG Group, Türkiye). The small saphenous vein was accessed percutaneously with a 21 gauge needle under Doppler ultrasound guidance, followed by the insertion of a 6F introducer sheath. A 0.035-inch guidewire was advanced through the introducer, and a 5F catheter was navigated over the guidewire to a position of 2 cm distal to the saphenopopliteal junction,

again under Doppler ultrasound guidance. A 2 mL volume of cyanoacrylate was prepared in a syringe using an injection gun and aspirator. The saphenopopliteal junction was then sealed using Doppler ultrasound to confirm closure. The catheter was retracted, and cyanoacrylate was injected into the target vein while applying pressure to the vein. After the injection, pressure was maintained on the vein for 30 seconds before concluding the procedure.

Radiofrequency Ablation

This procedure utilized the ClosureFast catheter (VNUS Medical Technologies, San Jose, CA, USA) following the manufacturer's guidelines. Local tumescent anesthesia was prepared with 20 ml of xylocaine (1%), 20 ml of sodium bicarbonate (8.4%), and 1 ml of adrenaline diluted in 500 ml of chilled saline. The small saphenous vein was accessed percutaneously with a 21G needle under Doppler ultrasound guidance, and a 6F introducer sheath was placed. The 6F ClosureFast catheter was then advanced to a position of 2 cm from the saphenopopliteal junction using Doppler ultrasound. Local tumescent anesthesia was injected into the saphenous fascia surrounding the target vein segment using a spinal anesthesia needle.

After the procedure in both patient groups, the treated limb was wrapped with an elastic bandage on the first day. According to the surgeon's preference, elastic compression stockings were worn for 30 days postoperatively in both groups. Although the literature and manufacturer guidelines for cyanoacrylate closure do not mandate the use of compression stockings, this practice was employed based on the surgeon's recommendation. The stockings used were either below-knee or above-knee, as recommended in the literature [6]. Both patient groups received a single dose of prophylactic antibiotics and analgesics at discharge. The primary outcome was complete occlusion of the treated vessel segment detected by CDUS. Side effects, complications and quality of recovery were assesed as secondary outcomes.

Statistical Analysis

Statistical analysis was conducted using SPSS version 20 (IBM Corp, Armonk, NY). To compare the continuous variables between the two treatment groups, the Student's t-test was employed. This test assumes that the data are normally distributed and that the variances of the two groups are equal. To assess these assumptions, normality was checked using the Shapiro-Wilk test, and equality of variances was evaluated with Levene's test. If the data did not meet these assumptions, the Mann-Whitney U test, a non-parametric alternative to the Student's t-test, was used.

For categorical variables, the Fisher's exact test was utilized. This test is appropriate for small sample sizes and does not require the assumption of a normal distribution. It assesses the association between categorical variables and is particularly useful when the expected frequency in any of the contingency table cells is less than 5.

To evaluate the recurrence rates and other binary outcomes, chi-square tests were applied where appropriate, assuming that the sample size was sufficiently large to meet the test's assumptions. The chi-square test assesses the differences in proportions between groups and assumes a sufficiently large sample size for valid results. A p-value of less than 0.05 was deemed statistically significant for all tests. The confidence intervals were calculated using the Z-distribution, which is appropriate when the sample size is large (n>30) and the data follow a normal distribution.

RESULTS

Between 2014 and 2019, 137 patients with small saphenous vein insufficiency who underwent cyanoacrylate and radiofrequency ablation for symptomatic varicose veins were included in the study. Of these procedures, 64 patients were treated with cyanoacrylate and 73 patients were treated with radiofrequency ablation. Preoperative baseline clinical and demographic characteristics of the patients are presented in Table 1. The mean age of the patients was 52.11±12.45 years in the CAC group and 50.46±9.76 years in the RFA group. There were 27 (42.1%) women in the CAC group and 35 (47.9%) women in the RFA group. The mean body mass index (BMI) was similar in both groups (p=0.624). The mean preoperative VCSS (venous clinical severity score) was 4.7±1.4 in the CAC group and 4.8±1.3 in the RFA group (p=0.427). At 1 year postoperatively, the mean VCSS was 1.6±1.2 in the CAC group and 1.1±0.8 in the RFA group (p=0.956). The mean VCSS at 1, 3 and 5 years postoperatively was statistically insignificant. The mean proximal diameter of the small saphenous vein was 6.35±1.76 in the CAC group and 6.12±1.45 in the RFA group. There were 14 (21.9%) patients with a proximal vein width of more than 6 mm in the CAC group and 17 (23.3%) patients in the RFA group. The results were similar in both groups (p=0.127). Similar results were obtained when the treated vessel length was compared for both groups (p=0.433). The distribution of patients according to CEAP classification is shown in Table 1.

Table 2 shows the complications and the occlusion rates seen as a result of intermittent doppler ultrasound controls after the procedure for both groups. DVT (deep vein thrombosis), ecchymosis and access site infection were not observed in both groups. Sural neuropathy was seen in 5 (6.8%) patients in the RFA group compared to none in the CAC group (p=0.058). Thrombophlebitis was seen in 2 (3.1%) patients in the CAC group compared to 1 (1.3%) patient in the RFA group (p=0.855). Post-procedure edema was seen in 1 (1.5%) patient in the CAC group and in 4 (5.4%) patients in the RFA group (p=0.234). Access site hematoma was seen in 1 (1.5%) patient in the CAC group and 2 (2.7%) patients in the RFA group. All these complications were similar in both patient groups and statistically insignificant.

When the patients were examined by Doppler ultrasound after the procedure, it was seen that all patients had successful

occlusion of the small saphenous vein. At 6 months, 4 (6.2%) patients in the CAC group and 3 (4.1%) patients in the RFA group had recurrence (p=0.22). At 1 year, 7 (10.9%) patients in the CAC group and 5 (6.8%) patients in the RFA group had recurrence (p=0.187). In the 2-year results, recurrence was found in 9 (14%) patients in the CAC group and 5 (6.8%) patients in the RFA group. At 6 months, 1 year and 2 years, the differences between the recurrence rates in both patient groups were statistically insignificant. At the end of 3 years, 11 (17.1%) patients in the CAC group and 5 (6.8%) patients in the RFA group had recurrence and this difference was statistically significant (p=0.045). At the end of 5 years, there was no change in the number of patients in the 3rd year when analyzed for recurrence. Recurrence was found in 11 (17.1%) patients in the CAC group and 5 (6.8%) patients in the RFA group. This difference was statistically significant (p=0.045).

In this study, a reaction similar to phlebitis was observed in some patients, which is scientifically referred to as a "phlebitis-like allergic reaction." This reaction, while noted to be relatively common, is not as frequent as it may seem based on the occurrence described in the literature. Despite its appearance, such reactions are generally managed effectively with appropriate medication. Upon discharge, the authors routinely prescribed anti-inflammatory and/or antihistaminic drugs to manage and alleviate symptoms associated with this reaction.

Phlebitis-like allergic reactions were monitored postoperatively, and the patients were advised to contact the clinic if symptoms persisted or worsened. The frequency of these reactions and the effectiveness of the prescribed medications were evaluated during follow-up visits.

This study assessed the efficacy of endovenous procedures in treating SSV insufficiency over five years. All treatment groups demonstrated significant improvements in clinical VCSS questionnaire scores (Figure 1).

There was no statistically significant difference in VCSS score between both groups during the 5-year follow-up after the procedures. In conclusion, both radiofrequency ablation and cyanoacrylate had similar results in the treatment of SSV in terms of patient satisfaction.

Table 1. Characteristics of patients

	CAC (n=64)	RFA (n=73)	All patients (n=137)	P value
Age	52.11±12.45 (95% CI: 49.06-55.16)	50.46±9.76 (95% CI: 48.22-52.69)	51.65±10.12 (95% CI: 49.95-53.34)	0.397
Gender				
Female	27 (42.1)	35 (47.9)	62 (45.2)	0.102
Male	37 (57.8)	38 (52.1)	75 (54.8)	
BMI, kg/m²	26.65±5.34 (95% CI: 25.34-27.95)	26.98±5.44 (95% CI: 25.73-28.22)	26.7±5.3 (95% CI: 25.81-27.58)	0.624
VCSS preprocedural	4.7±1.4 (95% CI: 4.35-5.04)	4.8±1.3 (95% CI: 4.5-5.09)	4.7±1.4 (95% CI: 4.46-4.93)	0.427
Postprocedural VCSS, 12 months	1.6±1.2 (95% CI: 1.3-1.89)	1.1±0.8 (95% CI: 0.91-1.28)	1.4±1.2 (95%CI: 1.19-1.6)	0.956
VCSS, 36 months	1.8±1.3 (95% CI: 1.48-2.11)	1.2±0.8 (95% CI: 1.01-1.38)	1.5±1.3 (95% CI: 1.28-.171)	0.934
VCSS, 60 months	2.4±1.7 (95% CI: 1.98-2.81)	1.6±1.3 (95% CI: 1.3-1.89)	1.9±1.6 (95% CI: 1.63-2.16)	0.566
Vein treatment length, cm	21.13±3.2 (95% CI: 20.34-21.91)	19.21±2.9 (95% CI: 18.54-19.87)	21.27±3 (95% CI: 20.76-21.77)	0.433
Proximal vein diameter, mm, mean	6.35±1.76 (95% CI: 5.91-6.78)	6.12±1.45 (95% CI: 5.78-6.45)	6.22±1.66 (95% CI: 5.94-6.49)	0.655
Proximal vein diameter				
<6mm	50 (78.1)	56 (76.7)	106 (77.4)	0.345
>6mm	14 (21.9)	17 (23.3)	31 (22.6)	0.127
Duration of procedure min	20.55±7.88 (95% CI: 18.61-22.48)	44.76±9.12 (95% CI: 42.66-46.85)	32.65±8.67 (95% CI: 31.19-34.1)	0.123
CEAP class				0.955
2	41 (64)	45 (61.6)	86 (62.7)	
3	13 (20.3)	12 (16.4)	25 (18.2)	
4	8 (12.5)	10 (13.6)	18 (13.1)	
5	1 (1.5)	5 (6.8)	6 (4.3)	
6	1 (1.5)	1 (1.3)	2 (1.4)	

Data are presented as n (%) or mean±standard deviation, DVT: deep vein thrombosis, BMI: body mass index, VCSS: venous clinical severity score, CEAP: clinical, etiology, anatomy, and pathophysiology, RFA: radiofrequency ablation, CAC: cyanoacrylate closure

Table 2. Complications and recurrences rates

	CAC (n=64)	RFA (n=73)	All patients (n=137)	p
DVT	0	0	0	-
Sural neuropathy	0	5 (6.8)	5 (3.6)	0.058
Ecchymosis	0	0	0	-
Thrombophlebitis	2 (3.1)	1 (1.3)	3 (2.1)	0.855
Edema	1 (1.5)	4 (5.4)	5 (3.6)	0.234
Access site hematoma	1 (1.5)	2 (2.7)	3 (2.1)	0.502
Access site infection	0	0	0	-
Recurrence				
Day 1	0	0	0	-
6 months	4 (6.2)	3 (4.1)	7 (5.1)	0.22
1 year	7 (10.9)	5 (6.8)	12 (8.7)	0.187
2 years	9 (14)	5 (6.8)	14 (10.2)	0.098
3 years	11 (17.1)	5 (6.8)	16 (11.6)	0.045
5 years	11 (17.1)	5 (6.8)	16 (11.6)	0.045

Data are presented as n (%) or mean±standard deviation, DVT: deep vein thrombosis, RFA: radiofrequency ablation, CAC: cyanoacrylate closure

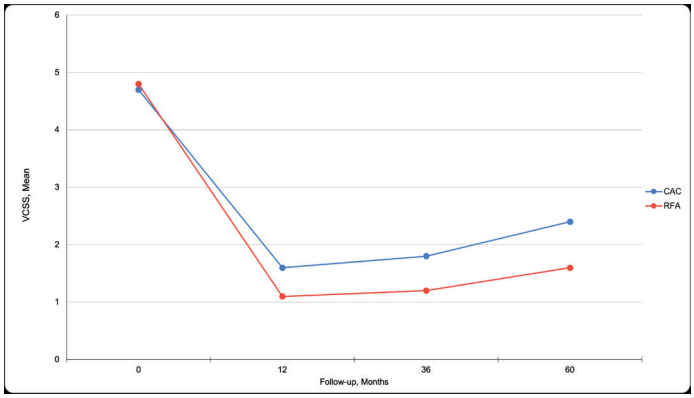

Figure 1. Mean Venous Clinical Severity Score (VCSS) comparison for both patient groups

DISCUSSION

Initially, thermal ablation techniques were predominantly based on laser technology. Subsequently, radiofrequency devices emerged as alternatives. These methods were developed as less invasive options compared to traditional open surgery for treating varicose veins [7-9]. Both techniques release substantial amounts of energy during the procedure. To mitigate the risks of burns and nerve damage to the skin and underlying tissues, tumescent anesthesia is required, which involves multiple injections into the leg. This can lead to complications such as hematoma and ecchymosis, and patients might need additional sedation to manage pain from these injections. While these complications are notable, the advancements in tumescent anesthesia techniques have greatly improved patient tolerance and outcomes over the years. To minimize these risks and to treat venous insufficiency using only local anesthesia, alternative approaches like foam sclerotherapy and cyanoacrylate ablation have been developed [10]. Numerous studies have evaluated and compared new and traditional treatment methods for venous insufficiency, examining their clinical outcomes and effectiveness. Some have also assessed the impact of different procedures, including open surgery, endovenous thermal ablation, and sclerotherapy, on patients' quality of life [11-14]. Our study focused on comparing radiofrequency ablation and cyanoacrylate embolization in terms of clinical outcomes and quality of life, using the VCSS scale for assessment.

Eroglu et al. found that at a 2-year follow-up, patients who underwent cyanoacrylate embolization showed a significantly greater improvement in VCSS scores compared to those who had radiofrequency ablation [15]. This suggests that while cyanoacrylate may offer initial advantages in patient-reported outcomes, long-term effectiveness and patient satisfaction must be considered comprehensively. Recent mid-term results also support the effectiveness of cyanoacrylate for treating varicose veins with high patient satisfaction and minimal complications [16-18]. In contrast, our study found that VCSS scores were better in the radiofrequency ablation group compared to the cyanoacrylate embolization group. This discrepancy highlights the need for further investigation into the long-term effects of different treatment modalities and their impact on quality of life.

Patient preference is a crucial factor in deciding the treatment approach. Contrary to Yang et al., our study observed a lower incidence of superficial phlebitis with radiofrequency ablation compared to cyanoacrylate treatments [19]. This finding

underscores the importance of individualized treatment plans based on patient-specific factors and expected outcomes. All endovenous treatments for venous insufficiency induce inflammation. The heat generated during radiofrequency ablation can lead to widespread inflammation in the surrounding soft tissues. Thus, effective tumescent anesthesia is essential to separate the treated vessel from adjacent tissues. While this approach minimizes direct thermal injury, it does not entirely eliminate the risk of inflammatory responses. Cyanoacrylate treatment also induces venous inflammation, with superficial phlebitis remaining a common complication. Some studies report painless skin reactions similar to phlebitis, with such reactions occurring in about 25% of patients following cyanoacrylate treatment [20,21]. The term "phlebitis-like allergic reaction" more accurately describes the reaction observed in this study, distinguishing it from true phlebitis. Although this reaction was encountered, it was not as prevalent as might be inferred from anecdotal reports. Routine prescription of anti-inflammatory and/or antihistaminic drugs has been shown to be effective in managing these symptoms, and their use was consistent with our clinical practice guidelines. Future studies could further elucidate the incidence of this reaction and optimize management strategies.

Another issue observed was a higher rate of persistent paresthesia following radiofrequency ablation, likely due to thermal damage to nerves around the treated vessel if tumescent anesthesia is inadequate. Nerve damage is a serious complication and a frequent cause of patient dissatisfaction [22]. Although this complication is relatively rare, its impact on patient quality of life can be significant. Paresthesia can affect about 20% of patients after radiofrequency ablation [23]. However, improved tumescent anaesthesia techniques have reduced this complication to 1-3% [23-25]. In the study by Budak et al., which involved radiofrequency ablation (RFA) in 52 patients, sural nerve damage was observed in 2 patients, accounting for 3.8% of the cases [26]. Ongoing refinement of these techniques will likely continue to improve patient outcomes and reduce the incidence of such complications.

We also encountered an adhesive abscess under the skin at the puncture site in two patients after cyanoacrylate treatment. Previous studies have noted similar complications, often related to the catheter removal process. These adhesive clumps can adhere to the catheter tip and, in some cases, act as foreign bodies in the subcutaneous tissue. Surgeons now routinely use ultrasound to check for and remove any clumps at the insertion site at the end of the procedure. This practice represents a proactive approach to minimizing post-procedural complications and improving patient safety.

This study has limitations due to its retrospective nature and potential gaps in pre-treatment symptom records and post-treatment complication data. Our follow-up period was longer compared to other studies, and we utilized standardized tests to assess patient quality of life. Ultrasound evaluations were performed by the treating surgeons, though asymptomatic venous abnormalities might be missed. Future prospective studies with larger sample sizes could provide more robust data and further validate our findings.

Venous insufficiency is typically not life-threatening, but often leads patients to seek treatment for cosmetic reasons in addition to pain, swelling, burning, cramping, and itching. Patients should be informed about the disease's pathogenesis, treatment options, complications, and potential cosmetic outcomes. Failure to communicate these aspects may result in patient dissatisfaction, especially among those with high aesthetic concerns. Effective communication and patient education are crucial in managing expectations and improving overall satisfaction with treatment outcomes.

As technology advances, it's crucial to evaluate and compare each new method with traditional treatments comprehensively. Given the prevalence of chronic venous insufficiency and its impact on quality of life, ongoing development of effective treatments remains a priority for vascular surgeons. In summary, endovenous procedures for treating venous insufficiency offer practical benefits and minimal early complications compared to open surgery. Continued innovation and research are essential to advancing treatment options and enhancing patient care.

The study's limitations include a relatively small sample size and its retrospective, single-center nature. The procedures were performed by two surgeons, which might introduce variability. Including a larger and more diverse patient population could yield different results.

CONCLUSION

In conclusion, endovenous procedures are effective and minimally invasive options for managing venous insufficiency. Radiofrequency ablation therapy and cyanoacrylate ablation show similar quality of life outcomes in terms of long-term follow-up. Further research with larger sample sizes is needed to validate these findings and improve success rates in treating venous insufficiency. Ongoing evaluation and refinement of treatment strategies will be crucial in optimizing patient outcomes and advancing the field of venous disease management.

Ethics Committee Approval: The research adhered to the principles outlined in the Declaration of Helsinki. The study was approved by the Research Ethics Board at Ankara University (approval date: July 18, 2024; reference number: 2024/444).

Patient Consent for Publication: Informed consent was obtained from each patient before the procedure

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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