

Outcomes of Radiofrequency Ablation Therapy of Great Saphenous Veins Insufficiency

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ABSTRACT

Objective: To evaluate the outcomes of radiofrequency ablation (RFA) therapy performed on patients with great saphenous vein insufficiency.

Study Design: Descriptive study.

Place and Duration of Study: Bahcelievler State Hospital, Istanbul, Turkey, between January 2018 and May 2021

Methodology: A total of 709 patients (382 females, 327 males), who were treated with radiofrequency ablation (RFA) in the clinic, were included in the study. The demographic, anthropometric, clinical, laboratory, and radiological data of the patients were obtained retrospectively from the medical records. Pre and post treatment clinical, etiologic, anatomical, pathophysiologic (CEAP) scores, the venous clinical severity score (VCSS), and the visual analog scale (VAS) were evaluated.

Results: The median age of the patients was 48 (19-65) years, and the median follow-up period was 36 (6-53) months. At follow-up, after treatment, 673 (94.9%) of the patients had a CEAP clinical score of C0. Postoperative complications were recorded in 56 (7.9%) patients. Significant improvement was observed in the patients' CEAP, VAS, and VCSS scores at the follow-up ($p < 0.001$).

Conclusion: There was a high success rate in achieving short- and long-term venous occlusion in varicose vein treatment with RFA. Characterized by a fast recovery, good perioperative and postoperative outcomes, and a low frequency of side effects, RFA is effective and safe in the treatment of varicose veins.

Key Words: *Chronic venous insufficiency, Radiofrequency ablation, Patient-reported outcomes.*

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INTRODUCTION

Varicose veins, one of the manifestations of chronic venous disease, are mostly characterised by swelling and enlargement of the lower extremity superficial veins, leading to various medical problems. It is thought to be associated with reflux and venous hypertension which occurs as a result of the dysfunction of the flexible one-way valves that prevent the backflow of blood in the veins.^{1,2} Its frequency increases with age and is more common in women. The estimated prevalence varies according to the evaluation criteria, the population, and the design of the study. The frequency of chronic venous disorders was reported to be between 30-55% and the frequency of varicose veins was reported to be between 10-29%.²⁻⁵ In the early stages, varicose veins cause only cosmetic problems, but if not treated in time, they can progress to venous ulcers that result in serious morbidity.

Although the treatment methods depend on the stage of the disease and vary from lifestyle changes to endovascular or conventional interventions. Radiofrequency ablation (RFA) is an endovenous thermal ablation technique which is minimally invasive method and has replaced surgical approaches due to shorter hospital stays, high success, and low complication rates.⁶ Venous occlusion and the absence of recurrent reflux are important indicators in the evaluation of RFA treatment success. High venous occlusion rates are reported, however there are limited studies showing the long-term (especially after 2 years) outcomes.⁷⁻¹⁰ The aim of this study was to evaluate the outcomes of RFA therapy performed on patients with varicose veins.

METHODOLOGY

Between January 2018 and May 2021, patients aged 19-65 years, who were found to have venous insufficiency of the great saphenous vein (GSV) (>5.5 mm diameter) accompanied by reflux (>0.5 seconds) detected by venous Doppler ultrasonography and were treated with RFA in the Cardiovascular Surgery clinic of Bahcelievler State Hospital, Istanbul, Turkey, were included in the study. The demographic, anthropometric, clinical, laboratory, and radiological data of the patients were obtained retrospectively from the medical records. The clinical, etiologic, anatomical, and pathophysiologic (CEAP) classifica-

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tion were used in determining whether to use RFA therapy from C0-C6. C0 was labelled without any visible or palpable sign. C1 was telangiectasias (1-3 mm diameter). C2 was a prominent varicose vein (>3 mm diameter). C3 was presence of edema. C4 was secondary skin changes. C5 was healed ulcer. C6 was open ulcer. The RFA was applied to the cases who were evaluated as C2-C6 according to the CEAP classification and with significant symptoms or cosmetic problems. Patients with a history of deep vein thrombosis, under anticoagulant therapy, and with concomitant peripheral artery disease, were excluded from the study.

The Visual Analog Scale (VAS), a numerical scale from 0 to 10, a tool widely used to measure pain, was applied to all the patients. The patients were asked to indicate the intensity of pain they felt on a specially prepared 10 cm line (0 representing no pain and 10 being significant pain). The VAS was applied to all the patients before the operation and one day after the RFA procedure. In addition, the Venous Clinical Severity Score (VCSS), which is one of the commonly used tools in the evaluation of venous insufficiency, was applied. The VCSS was calculated by evaluating 10 different parameters (venous edema, pain, skin pigmentation, inflammation, varices, ulcer presence, ulcer duration, induration, ulcer size, and compliance with compression therapy). The VCSS was evaluated at the time of hospitalisation of patient. Control VCSS was evaluated in the last examination of the patients. In addition, color Doppler ultrasonography (CDUS) was performed in the patients whose complaints such as pain and swelling did not resolve in the postoperative period and in the patients who developed any postoperative complications. Re-intervention was planned in the patients who developed recanalisation according to CDUS results.

Table I: Demographic and clinical characteristics of the study group.

	N	%
Gender		
Male	382	53.9%
Female	327	46.1%
Affected side		
Right	334	47.1%
Left	375	52.9%
Postoperative complications		
Major complication	0	0%
Minor complication	7	1%
	Mean ±SD	Median (min-max)
Age (years)	47.4 ±11.0	48 (19 - 65)
Follow-up time (months)	34.1±12.2	36 (6 - 53)
Venous diameter (mm)	6.9 ±0.6	7.1 (5.1-14.6)

Data were presented as numbers (%), mean ± standard deviation (SD) or median (minimum-maximum).

One mg of intravenous midazolam was administered for sedation and local anesthesia was applied to the intervention site. A 7F sheath was used for cannulation of the GSV. The tip of the RFA catheter (ClosureFast RFA System, Medtronic, USA) was positioned approximately 2 cm distal to the saphenofemoral junction. Then the tumescent solution was administered into

the surrounding tissues of GSV and followed by the ablation. At the end of the procedure, a mini phlebectomy was performed if necessary. The procedure was completed by applying an elastic bandage. All the patients were ambulated 1 hour after the intervention and discharged the same day. After removing the bandage, patients were advised to use compression stockings (22-30 mmHg) and venoactive drugs for 6 months.¹¹

Statistical analyses of the data was conducted using SPSS 21.0 (IBM, Armonk, NY). Data were presented as number (%), mean± standard deviation, and median (25th -75th percentiles). The Wilcoxon signed-rank test was used for comparison of the continuous data of pre- and post-operation scores and the marginal homogeneity test was used for the comparisons of categorical variables. In all the statistical tests, *p* values <0.05 were considered significant.

RESULTS

A total of 709 patients (53, 9%; 382 females, 46, 1%; 327 males) were included in the study. The median age of the patients was 48 (19-65) years, and the median follow-up period was 36 (6-53) months (Table I). At follow-up after treatment, 673 (94.9%) of the patients had a CEAP clinical score of C0. Postoperative complications were recorded in 7 (1%) patients (Table I).

The pretreatment CEAP score distribution of the patients was as follows: 595 (83.8%) patients C2, 49 (6.9%) patients C3, 16 (2.2%) patients C4, and 50 (7.1%) patients C5. Significant improvement was observed in the patients' VAS and VCSS scores at the follow-up (*p*<0.001, and *p*<0.001 respectively, Table III).

When the patients were divided into five groups in 12 months according to the follow-up period, the CEAP stages were similar before the treatment (Table II). There was a significant improvement in the CEAP clinical scores after the treatment (*p*<0.001, Table III).

DISCUSSION

In the current study, the clinical results of the RFA method applied in the patients with varicose veins were investigated using the VAS, VCSS, and CEAP classification which were evaluated in pretreatment and post treatment follow-ups. It was shown that there was a significant improvement after RFA treatment in all the parameters examined. The studies conducted in recent years, the average success rate of RFA in 3-month and 6-month follow-ups have been reported as approximately 98%.^{9,10,12-14} However, few studies have reported that the success rate, which is very high in the short-term follow-up of the RFA technique, may change overtime. The success of occlusion in RFA was between 76.7-100%^{8,9,15} at the end of the 1st year, between 85.2% - 95.8% at the end of the 2nd year,^{15,16} and 92.6% after 3 years,¹⁰ have been reported. In a study by Merchant *et al.* with 1,006 patients (1,222 limbs) in longer follow-ups, the success rate after 5 years of follow-up was reported as 83.5%.⁷

Table II: Change in CEAP scores according to postoperative follow-up time groups.

CEAP stage	Follow-up duration										Total (n=709)	
	<12 months (n=69)		12-24 months (n=72)		24-36 months (n=257)		36-48 months (n=231)		48-60 months (n=78)			
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
C1	-	64 (92.8%)	-	70 (97.2%)	-	238 (92.7%)	-	223 (96.5%)	-	78 (97.5%)	-	673 (94.9%)
C2	59 (85.5%)	2 (2.9%)	62 (86.1%)	1 (1.4%)	207 (80.5%)	6 (2.3%)	193 (83.5%)	4 (1.7%)	73 (91.3%)	0 (0%)	595 (83.8%)	13 (1.8%)
C3	7 (10.2%)	2 (2.9%)	5 (6.9%)	1 (1.4%)	18 (7.0%)	5 (1.9%)	16 (6.9%)	4 (1.7%)	3 (3.8%)	1 (1.3%)	49 (6.9%)	13 (1.8%)
C4	0 (0%)	1 (1.4%)	1 (1.4%)	0 (0%)	10 (3.9%)	6 (2.3%)	3 (1.3%)	0 (0%)	2 (2.5%)	1 (1.3%)	16 (2.3%)	8 (1.1%)
C5	3 (4.3%)	0 (0%)	4 (5.6%)	0 (0%)	22 (8.6%)	2 (0.8%)	19 (8.2%)	0 (0%)	2 (2.5%)	0 (0%)	50 (7.0%)	2 (0.3%)
C6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*CEAP: Clinical-etiological-anatomical-pathophysiological Classification.

Table III: Pre- and post-treatment comparison of the changes in the VAS, CEAP and VCSS scores of the study group.

CEAP stage	Pre-treatment		Post-treatment		p-value
	N (%)		N (%)		
1	0 (0.0)		673 (94.9)		<0.001*
2	595 (83.8)		13 (1.8)		
3	49 (6.9)		13 (1.8)		
4	16 (2.2)		8 (1.2)		
5	50 (7.1)		2 (0.3)		
6	0 (0.0)		0 (0.0)		
	Median (25 th -75 th percentiles)		Median (25 th -75 th percentiles)		
VAS	6 (3 - 8)		1 (0 - 1)		<0.001**
VCSS	6 (4 - 8)		1 (0 - 2)		<0.001**

Marginal homogeneity test (Monte Carlo) ***Wilcoxon signed-rank test; CEAP: Clinical, etiologic, anatomic, and pathophysiological; VAS: Visual analog scale; VCSS: Venous clinical severity score.

In the present study, the success of RFA treatment was 92.8% in the first 12 months, 97.2% between 12 to 24 months, 92.7% between 24 to 36 months, 96.6% between 36 to 48 months, and 97.6% between 48 to 60 months follow-up (overall success rate 94.9%) which is consistent with the literature review.

Venous insufficiency is a chronic disease that negatively affects the quality of life. Apart from the CEAP score which is the main indicator of treatment success, various parameters used in the evaluation of the effectiveness of the RFA treatment have been defined. Of them, VCSS has been approved and is a widely used method all over the world. Many studies, which utilised RFA, have reported that the VCSS scores of the patients improved significantly after treatment.¹⁷ In the present study, while the median VCSS score before treatment was 6 (25th-75th percentile, 4-8), the median score at the last follow-up significantly decreased to 1 (25th-75th percentile, 0-2) which is in line with the literature data. In addition, it has been reported that RFA treatment causes less postoperative pain compared to conventional surgery and EVLA treatment.^{12,15} The VAS change in this study supports these findings in the literature. Apart from these, all of the studied patients were discharged the same day and returned to their normal daily activities within a week. Moreover, it has been reported in various studies that better results are obtained in RFA compared to other techniques in terms of fast recovery, less perioperative pain, and improved quality of life.^{12,18-20} Considering the

different short and long-term evaluation parameters, it can be concluded that the RFA method provides better perioperative and postoperative outcomes.

The frequency of complications varies in studies. The frequency of deep vein thrombosis was reported to be between 0% and 3.5% and the frequency of pulmonary embolism was reported to be between 0.04% and 1.4%.^{9,21} Skin burns were less frequent in the RFA technique compared to EVLA suggesting the superiority of the RFA method.¹² Apart from these, infection and neurological damage were mentioned much less frequently.⁹ In this study, no major complications developed in any of the patients. Minor complications; paresthesia in one, thrombophlebitis in two, and erythema along the saphenous vein in four were observed in seven (1%) patients. However, these typical side effects were generally mild and all were resolved in a short time.

Some limitations with respect to this study should be acknowledged. First, there was no control group in which other treatment modalities (classical surgery, EVLA, etc.) were applied. Secondly, the postoperative follow-up period of the patients ranged from 6 months to 53 months and was therefore heterogeneous. Thus, patients were compared in 12-month follow-up groups, which may have affected the study results. Finally, this single-centred study was designed retrospectively and only the CEAP and VCSS scores at preoperative and most recent visits were considered. Since the CEAP and VCSS scores of the follow-ups at

certain intervals could not be obtained from the file records, therefore, the change in these scores over time could not be evaluated.

CONCLUSION

RFA technique used for lower extremity varicose vein treatment has a high technical success and low long-term recanalisation rates with low complication incidence.

ETHICAL APPROVAL:

The study was approved by Bakirkoy Dr Sadi Konuk Training and Education Hospital, Clinical Research Ethics Committee (Decision No. 2021/494, Date: 5.11.2021).

PATIENTS' CONSENT:

Informed consents were taken from all the patients who participated in this study.

COMPETING INTEREST:

The authors declared no competing interest.

AUTHORS' CONTRIBUTION:

MA: Supervisor, concept, design, data collection, data analysis, literature review, and critical review.

SA: Concept, design, literature review, and data collection.

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