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The clinical outcomes of endovenous radiofrequency ablation of varicose veins: two year follow-up results

Kronik venöz yetmezlik olgularında Endovenöz Radyofrekans Ablasyonun Klinik Sonuçları: İki Yıllık Takip Sonuçları

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ABSTRACT

Aim: Our aim was to evaluate the two-year results of radiofrequency ablation (RFA) in the treatment of great saphenous vein (GSV) insufficiency.
Methods: A total number of 217 patients who underwent RFA (52.5 % male, mean age 42.7±11.4) were included in the study. RFA was performed in patients with great saphenous vein valvular incompetence and saphenofemoral junction incompetence. Occlusion status was recorded by ultrasonography. Venous clinical severity score (VCSS) was calculated pre- and post-intervention.
Results: The mean follow-up period of the patients was 22.2 ± 5.1 months. Cumulative survival rate (Kaplan–Meier) of 24-month follow-up was 84.3%. Complete occlusion rate for GSV was 100%, 98.6% ,97.6%, 97.6% and 97.6% for 1, 6, 12, 18 and 24 months follow up, respectively. VCSS was significantly different before RFA and 4 weeks after RFA ($p < 0.001$). No major complications were observed in the study.
Conclusion: In the treatment of GSV insufficiency, RFA is a safely applied method with high occlusion rates and obvious VCSS score decrease.

Key words: Great saphenous vein insufficiency, radiofrequency ablation

ÖZ

Amaç: Çalışmamızda büyük safen ven (GSV) yetmezliğinin tedavisinde radyofrekans ablasyonun (RFA) iki yıllık sonuçlarını değerlendirmeyi amaçladık.
Yöntemler: Çalışmaya RFA uygulanan toplam 217 hasta (%52,5 erkek, ortalama yaş 42.7 ± 11.4) dahil edildi. RFA işlemi büyük safen vende kapak yetersizliği ve safenofemoral bileşkede venöz reflü olan hastalara uygulandı. Oklüzyon takibi doppler ultrasonografi ile yapıldı. Müdahale öncesi ve sonrası Venous clinical severity score (VCSS) kayıt altına alındı.
Bulgular: Hastalar ortalama 22.2 ± 5,1 ay takip edildi. 24 aylık takipte kümülatif sağkalım oranı (Kaplan-Meier) %84,3 idi. GSV için tam oklüzyon oranı 1, 6, 12, 18 ve 24 aylık
takiplerde sırasıyla % 100,% 98.6,% 97.6,% 97.6 ve% 97.6 idi. RFA işleminden önce ve RFA uygulandıktan 4 hafta sonra hesaplanan VCSS değerleri anlamlı ölçüde farklıydı ($p <0.001$). Çalışma sırasında önemli bir komplikasyon gözlenmedi.
Sonuç: GSV yetmezliğinin tedavisinde RFA, yüksek oklüzyon oranları ve belirgin VCSS skoru düşüşü ile güvenli bir şekilde uygulanan bir yöntemdir.

Anahtar kelimeler: Büyük safenöz ven yetmezliği, Radyofrekans ablasyon

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INTRODUCTION

Varicose veins are common in many populations, with prevalence ranging from 10.4 to 23.0% for men and 29.5 to 39.0% for women [1]. Due to its high incidence it has an important role in health expenditures [2]. Many treatment options are currently available for varicose veins, including compression stockings, high ligation of the saphenofemoral junction (SFJ) accompanied by stripping of the great saphenous vein (GSV) and minimally invasive procedures, such as radiofrequency ablation (RFA), endovenous laser ablation (EVLA), sclerotherapy and cyanoacrylate embolization. Minimally invasive procedures are associated with lower morbidity rates and faster recovery than conventional surgery [3]. In our study, we retrospectively analyzed 217 patients which have great saphenous vein insufficiency and were treated with RFA.

PATIENTS AND METHODS

Patients who underwent endovenous RFA to GSV due to venous insufficiency between 2017 and 2018, were evaluated retrospectively. Venous insufficiency was diagnosed by duplex ultrasound (USG) in standing position. A diameter below 2 cm for SFJ, a diameter above 5.5 mm for proximal GSV and reflux lasting longer than 2 seconds was assigned as the main criterion for endovenous RFA. Although they meet the main criteria, treatment of RFA was not performed in patients with chronic renal failure, known cardiac disease, uncontrolled hypertension, deep vein thrombosis (DVT), coagulation disorder, malignancy, history of another invasive venous treatment method, allergy to the tumescent anaesthesia solution and local or systemic infection. Treated lower limbs were classified according to the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) system. Before the procedure, patients' age, gender, body mass index (BMI), CEAP classification, GSV diameters and Venous clinical severity score (VCSS) scores were recorded. The study was approved by the local institutional Ethical Committee of Health Sciences University Bursa Higher Specialization Training and Research Hospital (Ethical Committee number: 2011-KAEK-25 2020/06-16).

Technique of Radiofrequency Ablation: We performed RFA under spinal anaesthesia in all cases. Knee level was preferred as the location of intervention to the GSV with insufficiency (Figure 1). The whole procedure was performed with the guidance of duplex USG. All treated GSVs had terminal valve incompetence. All interventions were performed by the same surgical team. The ClosureFAST (Covidien, Mansfield, Mass) catheter was used in all patients for the RFA procedure(Figure 2).

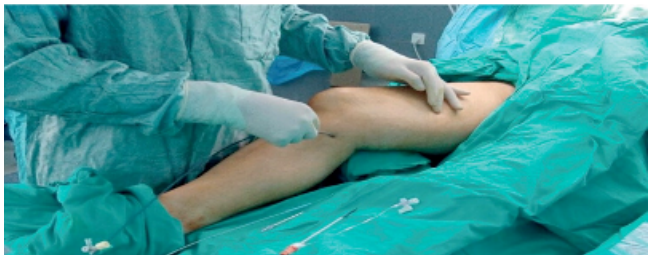

Figure 1. The location of intervention to the GSV.

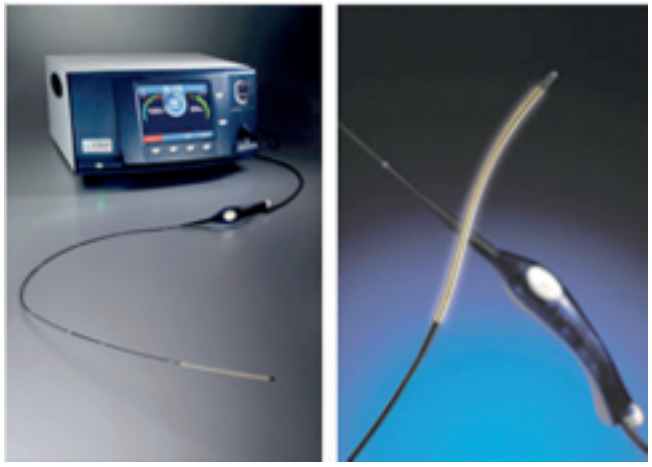

Figure 2. Covidien ClosureFast™ Endovenous Radiofrequency Ablation (RFA) Catheter.

After evaluating the GSV with duplex USG, intervention is performed with a 16 G - 70 mm needle. 7f sheath is applied to create the way to deliver the catheter. Through the sheath, the RFA catheter is delivered to the point where ablation will be initiated, again with USG guidance. The most appropriate point where the tip of the catheter is to be placed is 2 cm distal of the SFJ. To avoid heat damage, a classical tumescent anaesthetic mixture [4] consisting of 50 ml 1% lidocaine, 0.5 mg adrenaline and 10 ml 8.4% sodium bicarbonate and 450 ml isotonic NaCl was used (Figure 3). The average quantity was 350 to 450 mL. According to the manufacturer's recommendations in automatic mode, two cycles were performed for all segments. Each cycle consists of 20 seconds, that the 7 cm

active part of the catheter is kept at a constant temperature of 120 ° C.

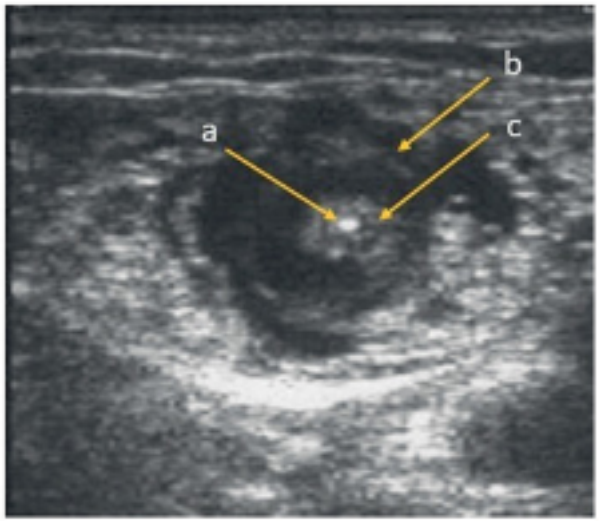

Figure 3. Tumescent anaesthetic application to avoid heat damage.

Following the procedure, an elastic bandage was applied around the extremity.

Compression therapy was performed for a period of two days.

Follow up protocol: All patients were followed at the outpatient clinic by the same surgeons. All phlebitis, edema, ecchymosis and any other complications were recorded. Duplex USG evaluation was performed in the standing position using a 9 MHz linear transducer (SonoSite Titan, SonoSite Ltd, Hitchin, UK). Duplex USG assessment results were classified as occluded vein (incompressible vein and no flow) and patent vein (partially incompressible vein and minimal flow pattern; compressible vein and presence of reflux for more than 2 s). All patients were evaluated using duplex USG at 4 weeks and 6, 12, 18 and 24 months after the procedure. In addition, clinical outcome measures were calculated using VCSS before and 4 weeks after the procedure.

Statistical analysis: Statistical analysis was performed with the Statistical Package for the Social Sciences (IBM SPSS Statistic Inc. Version 21.0, Chicago, IL, USA). Continuous and ordinal variables were expressed as mean ± standard deviation, and nominal variables were expressed as frequency and percentage. The Kolmogorov–Smirnov test of normality was used to identify the distribution of variables and the Wilcoxon signed ranks test was used to compare VCSS results before and 4 weeks after last endovenous RFA. Cumulative survival and complete occlusion rates were analyzed using the Kaplan–Meier method. For all tests, p value of <0.05 was considered statistically significant.

RESULTS

A total number of 217 patients who underwent RFA (52.5 % male, mean age 42.7±11.4) were recorded in the study. The demographic and clinical properties of the subjects are summarized in Table 1. The majority of patients (76%) were in the C3 and C4 groups according to the CEAP classification. The average size of the GSV was 7.9 ± 1.7 mm and the largest GSV diameter that was RFA applied was 14 mm (Table 1).

Table 1. Demographic features of the patients

	Patients n=217
Age (years)	42.7±11.4 (17-66)
Gender	
Male, n, %)	114 (52.5)
Female, n, %	103 (47.5)
BMI, kg/m2	27.4±4.2
Diamater of GSV(mm)	7.9±1.7 (6-14)
CEAP Class	
C2, n, (%)	48 (22.1)
C3, n, (%)	86 (39.6)
C4, n, (%)	79 (36.4)
C5, n, (%)	3 (1.4)
C6, n, (%)	1(0.5)
Baseline VCSS	6.4±1.2(4-10)
Follow-up time (Months)	22.2±5.1(1-24)

GSV: Great Saphenous Vein, CEAP: Clinical Etiologic Anatomic Pathophysiologic, VCSS: Venous Clinical Severity Score, BMI: Body Mass Index

The mean follow-up period of the patients was 22.2 ± 5.1 months. Due to the change of phone number and address, 34 patients could not be followed up clinically. Cumulative survival curve of RFA during follow up (Kaplan–Meier) was shown in figure 4 and the cumulative survival rate of 24-month follow-up was 84.3%. Complete occlusion rate for GSV was 100%, 98.6% ,97.6%, 97.6% and 97.6% for 1, 6, 12, 18 and 24 months follow up, respectively (Figure 5). GSV patency was observed in 5 patients among the patients that could be followed. While 3 of these patients

were detected at the 6th month of control, 2 were detected at the 12th month of the control. These patients underwent high SFJ ligation as an additional operation.

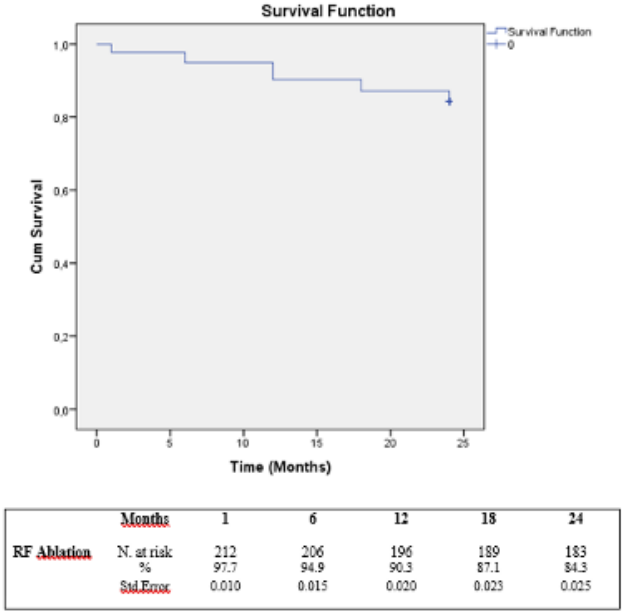

Figure 4. Kaplan–Meier survival curves of RF ablation during follow up. RF: Radiofrequency, N: Number of patients

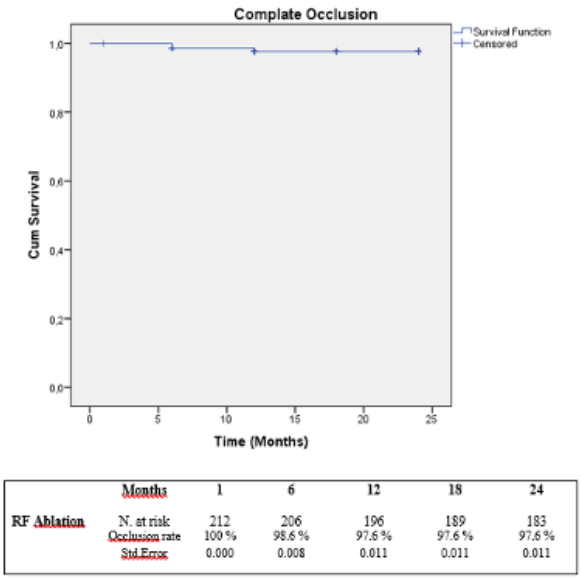

Figure 5. Kaplan–Meier cumulative complete occlusion rates of RF ablation. RF: Radiofrequency, N: Number of patients

We found that VCSS were 6.22±1.1 in preintervention and 1.3±0.5 in fourth weeks after RFA and found that VCSS was significantly different before and 4 weeks after RFA ($p < 0.001$, Wilcoxon Signed Ranks Test) (Table 2).

Table 2. Venous Clinical Severity Score results before and four weeks after RFA

	Before RFA	Four weeks after RFA	P value*
VCSS	6.22±1.1	1.3±0.5	< 0.001

RF: Radiofrequency ablation VCSS: Venous Clinical Severity Score, *Wilcoxon Signed Ranks Test

The most common postoperative finding was leg edema (26.7%), whereas local phlebitis occurred in 8 (3.7%) patients, and 42 (19.4%) patients complained of non-diffuse leg ecchymosis. Edema and ecchymosis findings improved after 2 weeks of medical treatment. In 14 (6.5 %) patients, palpable cordlike stiffness developed in the GSV region. Cordlike stiffness regressed within 2 months, except in one patient, whose cordlike stiffness was causing pain in limb movements and whose cordlike mass was removed surgically. In one patient (0.5 %), swelling was detected, after 1 month, in the region where the 7F sheath was inserted into the GSV with the Seldinger technique. The swelling was seen to be fluid in the USG and seroma was detected in the needle aspiration. With USG-guided needle aspiration, the seroma was emptied and a tight elastic bandage was applied. Although seroma was emptied twice, it continued to accumulate. Surgical exploration followed by vacuum treatment for 2 weeks was applied to the seroma region. When the accumulated amount was reduced to a minimum, capitonnage was performed surgically and seroma accumulation was not observed in the follow-up after surgery. DVT was not observed in any patient. Complications observed in patients are summarized in Table 3.

Table 3. Complications

	n=217
Edema, n,%	58 (26.7)
Ecchymosis, n,%	42 (19.4)
Palpable cordlike stiffness, n, %	14 (6.5)
Phlebitis, n,%	8 (3.7)
Seroma, n,%	1 (0.5)
Deep vein thrombosis	0

DISCUSSION

In present study, we investigated mid-term results of RFA in the treatment of varicose veins. We found that complete occlusion rates of GSV at 24 months of follow-up was %97.6. VCSS significantly

decreased after RFA at the first month follow-up. In addition, no life- threatening complications were observed.

The RFA method primarily effects to collagen matrix through heat-induced denaturation. Vein wall collagen contraction follows this effect. Shortly after, due to injury and inflammation of the vein wall, fibrotic sealing of the vessel lumen occurs [5]. Secondarily, endothelial denudation and swelling of the vein wall components occur due to heat-induced inflammatory processes. These mechanisms promise high rates of saphenous vein closure, therefore it has been claimed that it is an alternative treatment option to venous stripping, which leads to painful and prolonged post-operative recovery with high risk for hematoma formation, nerve damage and incidence of infection [6]. Consequently, due to improvement of the VCSS and CEAP levels after RFA procedure, the surgical treatment of symptomatic saphenous vein failure has evolved into less invasive endovenous treatments than GSV striping [7].

In a meta-analysis compiling randomized controlled studies presenting long-term results of endovenous procedures applied to the lower limb varices, no significant difference was found between RFA, EVLA or GSV striping in terms of recurrence rate, but RFA was reported to be superior to foam sclerotherapy with ultrasound [8]. Eroğlu et al. did not reveal a difference in their randomized controlled study comparing cyanoacrylate, RFA and EVLA procedures in respect to 2-year occlusion rates (occlusion rates were 92.6%, 90.9%, 91.5% respectively) (3). Bozoğlan et al. reported that the occlusion rates in their study that compare EVLA and RFA procedures, were respectively 100% and 94% after 6 months of follow-up [9]. In the study of 155 patients treated with RFA, Shepherd et al. reported 94.1% occlusion rate after an average follow-up of 12.2 months [10]. In another study evaluating only RFA results, they found occlusion rates as 94.6% -96% in the 2-year follow-up of the clinical results of RFA applied in 5 different centers in the Korean population [11]. In our study, similar to results of meta- analysis in the literature, comparative studies and studies in which the clinical results of RFA were published, we found the occlusion rate of 217 ClosureFastTM procedure to be GSV at 97.6% in a 24-month follow-up.

In a review evaluating frequently used quality of life and clinical scoring measurement techniques for venous diseases, it was found that VCSS was revised in 2010 and was the most common scoring method [12]. It is mentioned that VCSS is a scoring system that allows the measurement of minor changes in disease severity and enables evaluation of results at many levels such as technical success, patient reported success and clinical success. It is also mentioned that it has completed the CEAP classification. Our patients are routinely classified according to the CEAP classification and in our study as well, we evaluated the RFA procedure using VCSS scoring. In a study in which 12-month VCSS scores of RFA patients were evaluated, they stated that VCSS scores improved even in patients with recanalization after RFA [13]. Studies evaluating VCSS scores after endovenous RFA intervention have represented that the VCSS score is significantly reduced after the procedure [3,9-11]. In parallel with the literature, in our study, we found a significant decrease in the VCSS score after 4 weeks.

Similar to the literature, only minor complications were seen in present study (Table 3), and their quality of life improved one week after RFA and more improvement was observed in 12 months [3,9-11,14]. Since we recommend routine NSAIDs medication during the postoperative three-day follow-up, not many complaints of post-procedural pain were encountered, and postoperative pain was only observed in patients with phlebitis and cordlike stiffness. In the literature, among the complications that occur following endovenous procedures, we see the definition of "cord-like stiffness" in very few publications [9,11]. We consider that this situation is discussed under the title of thrombophlebitis. We think that vascular diameter, insufficient compression and insufficient leg elevation are effective in the development of cord-like stiffness. We found no evidence of classical phlebitis in our patients who developed cord-like stiffness in the GSV region: we encountered this complication in our study at a rate of 6.5%, and only one patient underwent surgical excision due to pain, but we think more studies investigating this clinical situation are needed. When we search

the literature, we were unable to find any seroma case in the region where the sheath was placed in the GSV, for the RFA procedure. Therefore, we think that our case may be the first, which we were able to treat with a series of procedures including puncture, compression, vacuum and surgical applications. We found that the treatment of seroma is challenging and therefore, although rare, it should be considered that it can develop at the puncture site. In early period of our RFA practice, we recommended enoxaparin for a week in the postoperative period and aspirin for a month, therefore the rate of ecchymosis was high in our series. However, our rate of ecchymosis was no higher than previous published studies, and a cure was achieved within two weeks [3,9,11] and we no longer administer this medication. Although DVT prevalence after RFA is believed to be between 0.2% and 1% [15], we did not observe any acute thrombosis or DVT in present study.

In a study comparing RFA with ligation and stripping, it was reported that most of the patients returned to their normal activities after the procedure, within 3-7 days [16]. Similarly, in our study, since spinal anaesthesia was performed in all our patients, they were all mobilized at the 6th postoperative hour, and all were discharged on the postoperative 1st day. The patients were advised to return to their normal activities within 3 days and to reprise work within a maximum of 5 days. We considered that this was a recommendation in accordance with the current literature [17].

Limitations: We have some limitations in present study, namely that that this was a retrospective effort. Additionally, the number of patients included in our study was small and it was not comparative.

Conclusion: RFA has improved patients' quality of life and our results are consistent with the results of studies in the literature. Consequently, we claim that RFA is a safe intervention that is successfully applied with high occlusion rates and significant VCSS score improvement in GSV failure.

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Conflict of interest: No conflict of interest was declared by the authors.

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