Cardiovasc Surg Int 2023;10(1):41-48
http://dx.doi.org/DOI: 10.5606/e-cvsi.2023.1490
www.e-cvsi.org

Cardiovascular Surgery and Interventions

Original Article Open Access

Radiofrequency ablation versus high ligation and stripping for the treatment of symptomatic great saphenous vein insufficiency: Short-term patient-reported outcomes

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Received: January 20, 2023 ***Accepted:*** March 02, 2023 ***Published online:*** March 27, 2023

ABSTRACT

Objectives: The study aimed to compare short-term patient-reported outcomes of radiofrequency ablation (RFA) versus high ligation and stripping (HLS) in a cohort with symptomatic great saphenous vein (GSV) insufficiency.

Patients and methods: This was a single-institution, retrospective, observational, cohort study of prospectively collected data. All procedures were performed between January 2019 and February 2021. Ninety-seven patients (54 females, 43 males; mean age: 45.2±11.1 years; range, 18 to 76 years) with lower limb chronic venous disease symptoms refractory to exercise, compression stockings, and pharmacotherapy underwent RFA (n=60) or HLS (n=37). Self-reported pain assessment was performed on the first postoperative day using the numeric rating scale, and duration of return to daily activities was questioned on the 30th postoperative day.

Results: Patients in the RFA group reported significantly less pain compared to patients in the HLS group with median numeric rating scale scores of 1.5 (0-4) versus 4 (2-5), respectively (p<0.001). The RFA group returned to their daily routine significantly sooner compared to the HLS group (1 [1-1] versus 1.5 [1-4] days, respectively; p=0.004).

Conclusion: Radiofrequency ablation is associated with significantly less postoperative pain and earlier return to daily activities compared to HLS in patients with symptomatic GSV insufficiency.

Keywords: Chronic venous disease, great saphenous vein insufficiency, high ligation and stripping, numeric rating scale, radiofrequency ablation.

Lower limb chronic venous disease (CVD) is a progressive and persistent condition that affects superficial, deep, and perforating venous pathways of the lower limbs.[1-3] With an estimated prevalence of 60 to 80%, CVD is responsible for at least 2% of the annual healthcare costs in developed countries.[2,3]

The main pathophysiological mechanism includes compromised venous return toward the right heart with subsequent blood reflux through involved venous segments.[2] Chronic venous reflux causes edema and structural changes in interstitial tissues and creates clinical symptoms associated with CVD.[2,3]

High ligation and stripping (HLS) has been the historical gold standard modality for the treatment of symptomatic patients who have axial great saphenous vein (GSV) reflux with or without saphenofemoral junction reflux, whereas newer thermal ablation techniques, including radiofrequency ablation (RFA), are being more and more commonly adopted.[4] Previous research has shown improved clinical outcomes after RFA in patients with CVD; however, patient-reported outcomes remain relatively understudied.[5,6] The present study aimed to compare short-term patient-reported outcomes of RFA versus HLS in a cohort with symptomatic GSV insufficiency.

PATIENTS AND METHODS

This was a single-institution, retrospective, observational, cohort study of prospectively collected data. All procedures were performed at the Department of Cardiovascular Surgery, Kartal Dr. Lütfi Kırdar City Hospital between January 2019 and February 2021. Consecutive patients who underwent surgery for lower limb CVD due to superficial vein incompetency were assessed for possible enrollment. Inclusion

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Citation:
Topcu AC, Ocal A. Radiofrequency ablation versus high ligation and stripping for the treatment of symptomatic great saphenous vein insufficiency: Short-term patient-reported outcomes. Cardiovasc Surg Int 2023;10(1):41-48. doi: 10.5606/e-cvsi.2023.1490

criteria were the existence of symptomatic lower limb venous insufficiency with duplex ultrasound (DUS) confirmation, Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) class C2-6 disease, and undergoing surgery for GSV insufficiency with either RFA or HLS. Exclusion criteria were being younger than 18 years of age, pregnancy, CEAP class C1 disease, undergoing surgery for small saphenous vein insufficiency, having CVD symptoms due to suprainguinal pathology, history of deep venous thrombosis, and undergoing treatment with any modality other than RFA or HLS (e.g., laser ablation, cyanoacrylate ablation, foam sclerotherapy, or mechanochemical ablation). A total of 103 patients were assessed for eligibility. After the exclusion of 6 patients, the remaining 97 patients (54 females, 43 males; mean age: 45.2±11.1 years; range, 18 to 76 years) who fulfilled the criteria were included in the study. Of these patients, 37 undergoing HLS made up the HLS group, and 60 patients undergoing RFA made up the RFA group (Figure 1). Patients were followed-up for 30 days.

Diagnosis and treatment

Patients with lower limb CVD symptoms refractory to exercise, compression stockings, and pharmacotherapy underwent DUS imaging in the upright position. Those who had grade 3 or 4 GSV incompetency were considered candidates for intervention. Disease severity was scored using CEAP classification and the Venous Clinical Severity Scale (VCSS). Patients with a GSV diameter of ≥5.5 mm at thigh level without focal dilation were offered to undergo RFA or HLS, and patients with a GSV diameter of <5.5 mm were offered to undergo HLS. Treatment modality was chosen following a patient-surgeon discussion including current evidence of short- and long-term outcomes and possible recurrence mechanisms. Preoperative surgeon-performed, duplex-guided vein mapping was done to mark incompetent GSV segments, incompetent perforators, and superficial varicosities in the upright position. Procedures were performed under general, spinal, or local anesthesia with real-time DUS guidance. Tumescent anesthesia was routinely used during RFA. Thermal ablation was performed at 120˚C in 7-cm segments starting 2 cm distally to the saphenofemoral junction in accordance with the manufacturer's recommendations (ClosureFast RFA System; Medtronic Inc., Minneapolis, MN, USA). Saphenofemoral junction tributaries were ligated during HLS. Perforating veins with reflux flow were ligated where needed, and superficial varicosities were treated by multiple stab phlebectomies during the same session. Patients were encouraged to mobilize as soon as possible after surgery. Treated legs were wrapped with elastic bandages for 24 h, and patients were advised to wear compression stockings afterwards.

Follow-up

All patients were seen at the outpatient clinic on the first, seventh, and 30th postoperative days. Procedural success was evaluated by DUS imaging and was defined as obliteration of the treated GSV segment. Complications were noted. Self-reported pain assessment was performed on the first postoperative day by instructing patients to mark the degree of pain on a numeric rating scale (NRS). The NRS is a scale designed to help patients report their pain level by circling a number from 0 to 10 on a paper strip with

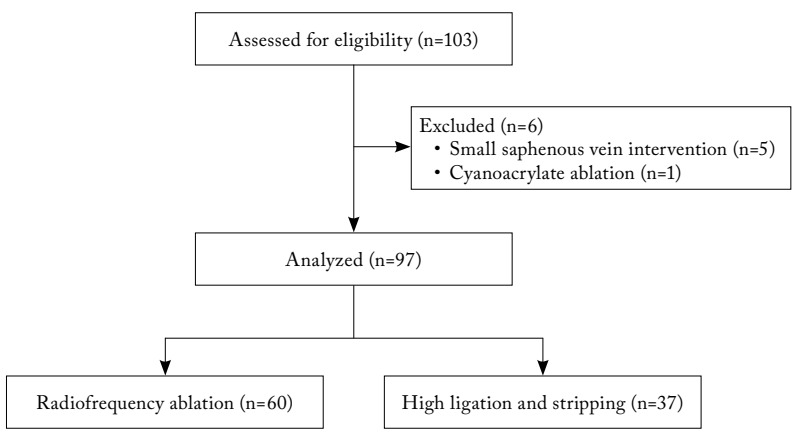

Figure 1. Flow diagram.

0 meaning "no pain" and 10 meaning "the worst pain you ever experienced." On the 30th postoperative day, patients were also questioned for the duration taken to return to daily activities by the question, "How many days did it take you to return to your normal daily activities after the procedure?"

Statistical analysis

Statistical analyses were performed using Jamovi version 2.2.5.0 (The Jamovi Project, Sydney, Australia). Qualitative variables were presented as absolute numbers (n) and frequencies (%). Frequencies were compared using Pearson's chi-squared test or Fischer exact test depending on expected number of observations. Histograms and the Shapiro-Wilk test were used for normality assessment of quantitative variables. Normally distributed quantitative variables were presented as mean ± standard deviation, and nonnormally distributed quantitative variables were presented as median and interquartile range. Means were compared using Student's or Welch's t-test according to the homogeneity of variances, and medians were compared using the Mann-Whitney U test. The level of statistical significance was set at a p value of <0.05.

RESULTS

The two groups were balanced in terms of demographics and comorbidities (Table 1). Thirty-eight (64.4%) patients in the RFA group had CEAP C2 disease, whereas 25 (69.4%) patients in the HLS group had CEAP C2 disease on physical examination (p=0.223). Venous Clinical Severity Scale scores were similar between groups (9.5 [7-12] in the RFA group *vs.* 8.5 [6.25-11] in the HLS group, p=0.270). Preoperative DUS revealed Grade 4 venous reflux in 58 (96.7%) patients in the RFA group and in 35 (94.6%) patients in the HLS group (p=0.635). The median GSV diameter was significantly larger in the RFA group (6.5 [5.7-8] mm *vs.* 5.45 [4.15-7.67] mm, p=0.005, Table 2).

Fifty-six (93.3%) patients in the RFA group received segmental treatment (55 above-knee and one below-knee ablation), whereas 11 (29.7%) patients in the HLS group underwent segmental treatment (11 above-knee stripping; p<0.001). Majority of patients in both groups were operated on with spinal or local anesthesia (57 [95%] patients in the RFA group *vs.* 34 [91.9%] patients in the HLS group, p=0.671, Table 2).

Table 1
Patient demographics

	All patients (n=97)					Radiofrequency ablation (n=60)				High ligation and stripping (n=37)				
	n	%	Mean±SD	Median	IQR	n	%	Mean±SD	Median	IQR	n	%	Mean±SD	Median	IQR	p
Age (year)			45.2±11.1					45.2±10.1					45.1±12.7			0.945[a]
Female sex	54	55.7				32	53.3				22	59.5				0.555[b]
Hypertension	16	16.5				11	18.3				5	13.5				0.534[b]
Diabetes	16	16.5				10	16.7				6	16.2				0.954[b]
Body mass index (kg/m^2)				27.5	24.8-31.1				27.2	25-31.6				27.8	24.1-30.3	0.294[c]

SD: Standard deviation; IQR: Interquartile range; a: Student's t-test; b: Pearson's chi-squared test; c:Mann-Whitney U test.

Table 2
Operative details

	All patients (n=97)				Radiofrequency ablation (n=60)				High ligation and stripping (n=37)				
	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	*p*
CEAP class													0.223[a]
C2	63	66.3			38	64.4			25	69.4			
C3	19	20			10	16.9			9	25			
C4	5	5.3			3	5.1			2	5.6			
C5	3	3.2			3	5.1			0	0			
C6	5	5.3			5	8.5			0	0			
VCSS score			9	7-12			9.5	7-12			8.5	6.25-11	0.270[b]
Venous reflux													0.635[c]
Grade 3	4	4.1			2	3.3			2	5.4			
Grade 4	93	95.9			58	96.7			35	94.6			
Vein diameter (mm)			6.4	5.35-7.9			6.5	5.7-8			5.45	4.15-7.67	**0.005*[b]**
Treated segment													**<0.001*[a]**
Complete GSV	30	30.9			4	6.7			26	70.3			
Above- or below-knee GSV	67	69.1			56	93.3			11	29.7			
Type of anesthesia													0.671[c]
General	6	6.2			3	5			3	8.1			
Regional/local	91	93.8			57	95			34	91.9			

IQR: Interquartile range; CEAP: Clinical, Etiological, Anatomical, and Pathophysiological; VCSS: Venous Clinical Severity Scale; GSV: Great saphenous vein; a: Pearson's chi-squared test; b: Mann-Whitney U test; c: Fisher exact test; * p<0.05.

Surgical success was achieved in all patients. No patients were lost to follow-up. Patients in the RFA group reported significantly less pain compared to patients in the HLS group with median NRS scores of 1.5 (0-4) versus 4 (2-5) (p<0.001). The RFA group returned to their daily routine significantly sooner compared to the HLS group (1 [1-1] *vs.* 1.5 [1-4] days, p=0.004). Median length of hospital stay and complication rates were statistically similar between groups (Table 3).

DISCUSSION

Results of the present study demonstrate that patients undergoing RFA for the treatment of GSV insufficiency experience significantly less pain on the first postoperative day, and they return to their daily routine significantly sooner compared to patients undergoing HLS. Our analysis also revealed excellent success rates for both procedures in a 30-day follow-up. These findings correlate with previous research reporting better or comparable short- and long-term outcomes with RFA compared to HLS.[7-9] In a randomized clinical trial of 88 patients, Subramonia and Lees[7] concluded that RFA was superior to HLS in terms of short-term outcomes, including postoperative pain and time to return to full level of household activities. However, they also concluded that this superiority would not be significant in the long term if recurrence and risk of reoperation were taken into account.[7] Another randomized clinical trial by Helmy ElKaffas et al.[8] reported lower complication rates for RFA in the short term and similar recurrence rate in the long term compared to HLS. Shaikadov et al.[9] revealed that patients undergoing RFA had significantly less postoperative pain compared to patients undergoing HLS in their multicenter analysis. One-year recurrence rates were also reported to be similar in that study.[9] We only had 30-day follow-up data, therefore cannot comment on long-term success rates.

Both groups had similar clinical and radiological features except for a significantly larger median GSV diameter in the RFA group. This significant difference was a direct result of reimbursement regulations regarding endovenous RFA treatment, as the Social Security Institution requires patients to have a GSV diameter of ≥5.5 mm for the compensation of an RFA device. Although it was not an objective of our study, considering that patients with larger and smaller veins

Table 3
Outcomes and complications

	All patients (n=97)				Radiofrequency ablation (n=60)				High ligation and stripping (n=37)				*p*
	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	
Obliteration of the treated segment	97	100			60	100			37	100			
NRS			2	0-5			1.5	0-4			4	2-5	**<0.001**[*a]
Return to daily activities (day)			1	1-2			1	1-1			1.5	1-4	**0.004**[*a]
Length of hospital stay (day)			1	1-1			1	1-1			1	1-1	0.128[a]
DVT	0	0			0	0			0	0			
Superficial phlebitis	3	3.1			1	1.7			2	5.4			0.556[b]
Infection	2	2.1			1	1.7			1	2.7			1.000[b]
Skin burn	2	2.1			1	1.7			1	2.7			1.000[b]
Focal paresthesia	1	1.0			0	0			1	2.7			0.381[b]

IQR: Interquartile range; NRS: Numeric rating scale; DVT: Deep vein thrombosis; a: Mann-Whitney U test; b: Fisher exact test; * p<0.05.

(RFA and HLS groups, respectively) had similar demographic, clinical, and radiological findings and outcomes, our results show that vein diameter should not be an indicator of necessity for intervention for venous insufficiency. A prospective cohort study from a national registry reported similar results.[10] They compared CEAP classes, VCSS scores, and patient-reported outcomes before and after treatment in patients with a vein diameter of ≥5 mm versus <5 mm, revealed similar symptomatic improvement rates between groups, and concluded that patients should not be denied for intervention based on vein size.[10] There is a discrepancy regarding the inclusion/exclusion of patients based on vein size among previous research. Sincos et al.[6] included patients with a vein diameter of 5 to 12 mm, whereas Subramonia and Lees[7] included those with 3- to 12-mm veins. Helmy ElKaffas et al.[8] did not apply a minimal threshold for the vein diameter, and their maximal threshold was 18 mm. We were able to successfully treat patients with relatively large veins using RFA, therefore believe that large GSV diameter should not discourage surgeons from utilizing this minimally invasive technique for their patients. In fact, Shaikadov et al.[9] demonstrated improved outcomes after RFA compared to HLS in patients with a GSV diameter of ≥14 mm.

Our analysis showed that the majority of patients in the RFA group underwent above-knee treatment, unlike the HLS group, in which the majority underwent complete stripping. We observed similar rates of paresthesia in both groups. There is conflicting evidence from previous research regarding treatment length and nerve injury.[11-15] A recent single-center, retrospective analysis by Liu et al.[11] revealed better outcomes, including less nerve injury, less operative bleeding, reduced operative time, and shorter hospitalization in patients treated with a modified above-knee technique versus those treated by complete stripping. On the contrary, Uncu[12] reported acceptable nerve injury rates in his single-surgeon experience of 102 procedures. There is also ongoing debate on whether proximal or distal stripping is superior to each other with regards to nerve injury.[13-15] Below-knee treatment with endovenous thermal ablation techniques has been mainly avoided due to close anatomical relationship of sensory nerves with superficial veins in the crus. Nerve injury during endovenous thermal ablation treatment of the small saphenous vein is well-studied, unlike during below-knee GSV ablation.[16,17] However, there are recent reports with successful thermal ablation treatment of whole-length or below-knee GSV insufficiency with acceptable nerve injury rates.[18,19] We performed below-knee RFA in patients with crural GSV insufficiency and did not observe nerve injury afterward. Further research is needed to assess safety of thermal venous ablation of below-knee superficial veins.

Groups were comparable in terms of complications, and our complication rates were similar to or lower than results of previous reports.[20-26] This result could have been altered depending on complication definitions. For example, ecchymosis or hematoma, adverse events that are expected to be more common after HLS, were not included in our analysis.

Other researchers reported shorter postintervention hospitalization durations after RFA compared to HLS, whereas length of hospital stay was similar between groups in our study.[6,8] This was most probably due to widespread use of spinal anesthesia in our cohort, which rendered patients to stay longer in the bed after procedures. Others mostly used local anesthesia during RFA, and spinal block or general anesthesia during HLS, therefore observed significantly shorter lengths of stay after RFA.[6,8] Unlike conventional surgery, endovenous ablation techniques can also be performed in outpatient settings.[23] When performed under local anesthesia in the office setting, RFA is associated with significantly reduced hospitalization rates and reduced costs compared to HLS performed in the operating theater.[27-29] Cost-effectiveness was out of the scope of our study. Future research should include this variable when comparing different treatment modalities for venous disease.

There are some limitations to this study. The follow-up duration was short; therefore, we were not able to analyze more robust outcome measures, such as long-term obliteration rates, long-term patient-reported outcomes, and long-term CEAP and VCSS scores. Cost-effectivity analysis could not be performed.

In conclusion, radiofrequency ablation is associated with significantly less postoperative pain and earlier return to daily activities compared to HLS in patients with symptomatic GSV insufficiency. Both procedures have high success and low complication rates in a 30-day follow-up.

Ethics Committee Approval: The study protocol was approved by the Kartal Dr. Lütfi Kırdar City Hospital Clinical Research Ethics Committee (date: 24.04.2019; no: 2019/514/152/4). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

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

Author Contributions: Idea/concept, design, control/supervision, data collection and/or processing, analysis and/or interpretation, literatüre review, writing the article, critical review, references and funding, materials, approval of the final version: A.C.T.; Idea/concept, design, critical review, approval of the final version: A.O.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding: The authors received no financial support for the research and/or authorship of this article.

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