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Comparing the Efficacy of Radiofrequency Ablation Versus Laser Ablation for Chronic Venous Insufficiency in the Lower Extremities: a Vietnamese Report

Tran Anh Tuan[1], Nguyen Minh Duc[2,3], Le Nguyet Minh[1], Hoang Duc Ha[4], Vu Dang Luu[1,5], Pham Minh Thong[1,5]

[1]Department of Radiology, Bach Mai Hospital, Hanoi, Vietnam

[2]Department of Radiology, Pham Ngoc Thach University of Medicine, Ho Chi Minh City, Vietnam

[3]Department of Radiology, Children's Hospital 2, Ho Chi Minh City, Vietnam

[4]Department of Radiology, Haiphong University of Medicine and Pharmacy, Hai Phong, Vietnam

[5]Department of Radiology, Hanoi Medical University, Ha Noi, Vietnam

Corresponding author: Nguyen Minh Duc, MD. Department of Radiology, Pham Ngoc Thach University of Medicine, Ho Chi Minh City, Vietnam. E-mail: bsnguyenminhduc@pnt.edu.vn. ORCID ID: http//www.orcid.org/0000-0001-5411-1492.

ABSTRACT

Introduction: Chronic venous insufficiency (CVI) is a chronic condition, triggered by reflux through the saphenous vein network. **Aim:** To determine the efficacy of endovenous laser ablation (LA) and radiofrequency ablation (RFA) for CVI treatment in the lower extremities, at the Bach Mai Radiology Center. **Methods:** This retrospective study was approved by the institutional review board of Bach Mai Hospital. The study recruited 49 people, from August 2016 to April 2018, with recurrent venous insufficiency in the lower extremities and measured 56 ablated veins. **Results:** In this study, 8 patients (10 veins, with a mean diameter of 5.83 ± 0.96 mm) were treated with RFA, and 41 patients (46 veins, with a mean diameter of 7.96 ± 3.47 mm) were treated with LA. The occlusion rates for LA- and RFA-treated veins were very effective, at 95.7% and 90%, respectively. No significant differences in occlusion rates or clinical improvements were observed between the two ablation methods. On the first day post-treatment, the visual analog score (VAS) value for the LA group was significantly higher than that for the RFA group. Furthermore, ecchymosis, 1 day after treatment, and hyperpigmentation, paresthesia, and numbness, 1 month after treatment, were only observed in the LA group. **Conclusion:** Both LA and RFA were minimally-invasive and safe therapies. No serious complications requiring further interventions were reported and the treatment effectively improved the clinical symptoms of patients. Based on our study, we recommend that RFA should be considered for moderate dilated saphenous vein cases, whereas LA should be indicated for large dilated saphenous vein cases, with or without aneurysm.

Keywords: Chronic venous insufficiency, Endovenous laser ablation, Endovenous radiofrequency ablation.

1. INTRODUCTION

Chronic venous insufficiency (CVI) in the lower extremities is a persistent disorder, caused by reflux through the network of saphenous veins. CVI evolves slowly, over a long period of time, negatively impacting cosmetic comfort and the quality of life for patients. Treatments using conservation methods, such as elastic compressive stockings and venoactive drugs, were initially established during the 1990s, require regular visits, and are time-consuming, whereas surgical therapies, such as ligation, stripping, and venous phlebectomy, require long hospitalization durations and are associated with high complication rates (1).

Following the advent of endovascular therapy, several studies have demonstrated the acceptability and efficacy of this treatment modality, which is associated with reduced hospitalization durations and lower adverse event risks, representing an effective cure for CVI in the lower extremities. Endovenous laser ablation (LA), which was used for the first time in 1989 by Puglisi, has become a common therapy for CVI in the lower extremities, with a high technical success rate, worldwide (2). LA, which utilizes lasers with wavelengths ranging from 810 to 1,470 nm, has been shown to be very efficient and has been associated with fewer complications after intervention. As an alternative to LA treatment, endovenous radiofrequency ablation (RFA) is another minimally

invasive treatment for patients with CVI in the lower extremities (3-5).

Both the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) suggested that endovenous thermal ablation be used as a first-line treatment for CVI in the lower extremities (3-5).

In Vietnam, the number of CVI patients who have received both types of ablation has increased during recent years. However, no studies have examined LA and RFA outcomes among Vietnamese patients with CVI in the lower extremities.

2. AIM

In this study, therefore, we intended to determine the initial short-term outcomes of LA using a 1470-nm wavelength relative to the short-term outcomes of RFA for the treatment of CVI in the lower extremities.

3. MATERIALS AND METHODS

The Institutional Review Board of Bach Mai Hospital approved this retrospective study. Between August 2016 and April 2018, 49 patients with CVI were enrolled in this study through the interventional unit of Bach Mai Radiology Center. Prior to treatment, patients were assessed, based on clinical, etiology, anatomy, and pathophysiology (CEAP) classification and the severity of clinical presentation, according to the venous clinical severity score (VCSS). Then, patients were assessed for saphenous veins via ultrasonography.

The patients were divided into two groups. One group received LA treatment, using the Nevertouch Direct procedure kit and the VenaCure 1470-nm laser system (AngioDynamics Netherlands BV) (n = 41, with total veins = 46), whereas the other received RFA treatment, using the RF medical ablation system (BVM Medical Limited) (n = 8, with total veins = 10). Local anesthesia was applied to the puncture position, followed by sheath insertion into the saphenous vein. Then, a catheter was inserted until its tip was 2 cm away from the saphenous-femoral junction (for the great saphenous vein) or the saphenous-popliteal junction (for the small saphenous vein), guided by ultrasonography. Perivascular anesthesia was performed, from the puncture site to the saphenous-femoral junction, by injecting a solution containing 0.1% lidocaine and 0.9% normal saline. In this study, all patients were discharged 2 hours after the intervention. Patients were re-examined by clinicians 1 day and 1 month after treatment. More specifically, 1 day after treatment, patients were evaluated for intermediate complications and reported their pain levels, using the visual analog scale (VAS). One month after treatment, patients were evaluated for complications, clinical manifestations, as assessed using the VCSS, and the occlusion rate of ablated veins, as assessed by ultrasonography.

SPSS, version 22.0 (IBM corp., New York, USA) was used to analyze data. Qualitative variables are presented as the number and percentage, whereas quantitative variables are presented as the mean and standard deviation. The chi-squared test or Fisher's exact test was used to compare qualitative variables, whereas Student's T-test or ANOVA was used to compare quantitative variables. P-values less than 0.05 were considered significant.

4. RESULTS

As shown in Table 1, the female/male ratio was 2.5/1. The mean age of the study population was 50.8 years, with no significant difference between females and males ($p > 0.05$). The mean symptom duration was 14.3 years. The mean body mass index (BMI) of the study population was 22.5. Only 29 patients (59.2%) had BMI values below 23, whereas 11 patients (22.4%) were overweight, and 9 patients (18.4%) were obese. The baseline VCSS value of the female group was significantly higher than that of the male group ($p < 0.05$).

Basic characteristics	Overall (n = 49)	Female (n = 35)	Male (n = 14)	P-value
Age (years)	50.8 ± 14.8	49.1 ± 15.0	55.3 ± 13.6	0.186
Symptom duration (years)	14.3 ± 11.8	14.4 ± 9.4	14.2 ± 16.9	0.967
BMI (kg/m2)	22.5 ± 3.2	22.8 ± 3.5	21.7 ± 1.8	0.277
VCSS before treatment	7.9 ± 3.2	8.5 ± 3.0	6.2 ± 3.1	0.022§

Table 1. Basic patient characteristics, according to gender. § Statistically significant.

As shown in Table 2, no significant differences were observed for symptom durations among the different clinical stages, as assessed by CEAP classification ($p > 0.05$). Most patients were classified as CEAP Stage 2, in which the varicose veins are visible, causing cosmetic disturbance.

CEAP classification	Overall (n = 49)	Symptom duration (years)	P-value
C2	43 (87.8%)	14.5 ± 12.4	0.957
C3	4 (8.2%)	13.2 ± 8.3	
C4	2 (4.0%)	12.5 ± 7.8	

Table 2. Symptom durations associated with the different CEAP stages.

As shown in Table 3, 7 patients were treated for bilateral veins. Therefore, the study examined a total of 56 ablated veins, including 46 veins (82.1%) treated with LA and 10 veins (17.9%) treated with RFA. The mean diameter of the LA-treated veins was significantly higher than that of the RFA-treated veins ($p < 0.05$). However, no significant difference was observed for the length of saphenous veins between the two ablation methods ($p > 0.05$).

Venous parameters	LA veins (n = 46)	RFA veins (n = 10)	P-value
Diameter of saphenous veins (mm)	7.96 ± 3.47	5.83 ± 0.96	0.001§
Saphenous vein with aneurysm (mm)	15 (32.6%)	1 (10%)	0.001§
Length of ablated saphenous veins (cm)	39.95 ± 10.31	42.85 ± 12.29	0.439

Table 3. Characteristics of treated veins, according to treatment method. § Statistically significant.

After 1 day of treatment, no deep venous thrombosis cases were observed. Ecchymosis was not observed after RFA, whereas 17 cases were reported after LA ($p < 0.05$)

(Table 4). The mean VAS score reported by the LA group 1 day after treatment was significantly higher than that reported by the RFA group ($p < 0.05$).

Adverse events 1 day after treatment	LA veins (n = 46)	RFA veins (n = 10)	P-value
Ecchymosis	17 (36.9%)	0	0.023§
VAS score	3.0 ± 1.4	0.3 ± 0.9	0.001§

Table 4. Adverse events one day after treatment, according to ablation method. § Statistically significant.

As shown in Table 5, VCSS values decreased significantly one month after treatment, compared with pre-treatment scores, for both groups. No significant difference in VCSS reduction was observed between the two ablation methods ($p > 0.05$).

VCSS	Overall (n = 49)	LA patients (n = 41)	RFA patients (n = 8)	P-value
Before treatment	7.9 ± 3.2	7.6 ± 3.3	9.0 ± 2.5	0.262
1 month after treatment	1.7 ± 2.0	1.7 ± 2.1	1.8 ± 1.4	0.898
VCSS reduction 1 month after treatment	6.2 ± 2.7	6.0 ± 2.7	7.2 ± 2.6	0.231

Table 5. VCSS follow-up one month after treatment, according to ablation method.

As shown in Table 6, 94.6% of saphenous veins were completely thrombosed, with only 3 cases (5.4%) of incomplete thrombosis reported for the middle of the saphenous vein; however, no reflux was observed by ultrasonography during the muscular compression test. Among the varicose veins, 80.4% were occluded, whereas 19.6% remained incompletely thrombosed; however, even the incompletely thrombosed varicose veins decreased in diameter and did not demonstrate reflux, as assessed by ultrasonography during the muscular compression test. Overall, no significant differences were observed between the two ablation methods ($p > 0.05$) (Figures 1 and 2).

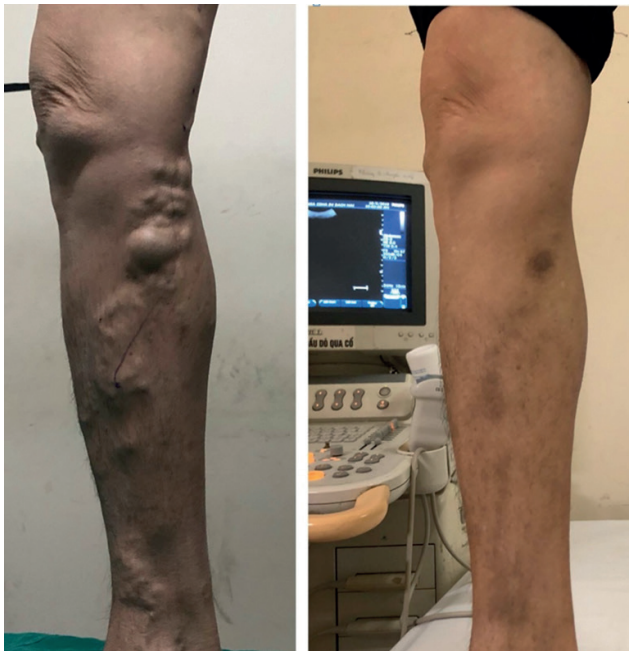

Figure 1. 56-year-old, female patient with CVI in the right GSV (left image). VCSS before treatment was 6. One month after LA, varicose veins were completely resolved (right image).

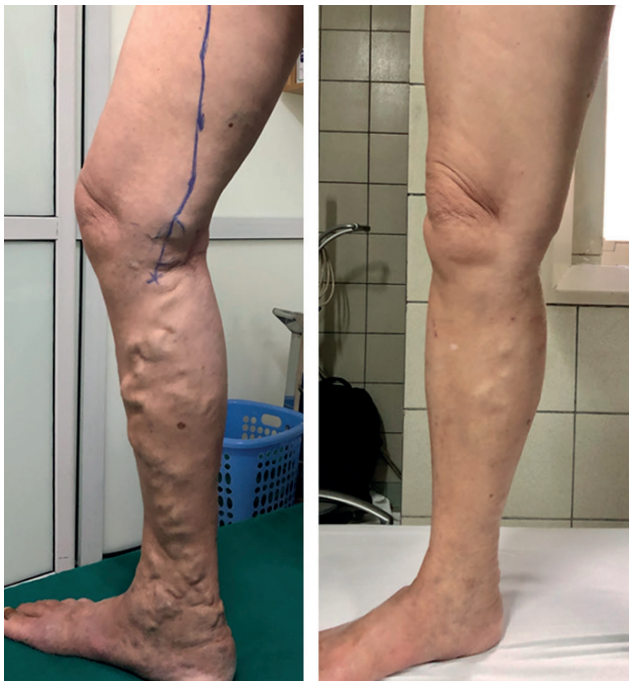

Figure 2. 65-year-old, male patient with CVI in the right GSV (left image). VCSS prior to treatment was 9. One month after RFA, varicose veins were completely resolved (right image).

Venous occlusion	Overall (n = 56)	LA veins (n = 46)	RFA veins (n = 10)	P-value
Complete thrombosis of ablated vein	53 (94.6%)	44 (95.7%)	9 (90%)	0.452
Occluded varicose veins after ablation	45 (80.4%)	37 (80.4%)	8 (80%)	0.637

Table 6. Thrombosis assessment results, via ultrasonography, 1 month after intervention.

As shown in Table 7, 1 month after intervention hyperpigmentation was the most common adverse event observed in LA patients. Furthermore, one case reported paresthesia and two cases reported numbness in the calf after LA. No complications were observed after RFA.

Adverse events	LA patients (n = 46)	RFA patients (n = 10)
Hyperpigmentation	11 (23.9%)	0
Paresthesia	1 (2.2%)	0
Numbness	2 (4.3%)	0

Table 7. Adverse events one month after treatment.

5. DISCUSSION

Venous insufficiency is a chronic disease that results in deteriorating quality of life, and the symptom duration reported by patients was always long-lasting, generally several years. The use of the VCSS for evaluation, both prior to treatment and during follow-up, has been approved by the US Food and Drug Administration (FDA), and the VCSS has been widely used in the USA. The VCSS a simple and convenient tool that can provide abundant information regarding clinical presentation, including pain, varicose veins, edema, eczema, and ul-

cers. In this study, we observed significant symptom reductions one month after ablation in both the LA and RFA groups. Our results were in agreement with those reported by previous studies (6-9).

A previous report has limited LA indications to saphenous veins without associated aneurysm (5). In our study, saphenous veins with aneurysms were ablated by adjusting the catheter revocation rate to a slower velocity relative to the standard reference. Our findings showed that LA successfully ablated 32.6% of saphenous veins with aneurysm, without severe complications. Although the mean diameter of saphenous veins treated with LA was considerably larger than that for veins treated by RFA, the potency of these two types of ablation was nearly identical. Our results are in line with those reported by previous studies (10-13)

In this study, the technical successful rate of LA and RFA reached 95.7% and 90%, respectively ($p > 0.05$). Data from previous experiments found that the potency of RFA was equivalent to LA when using lower wavelengths, such as 810 nm or 980 nm (9,14,15). However, the efficacy of LA when using a 1470-nm wavelength has been reported to be marginally higher than the efficacy of RFA for larger diameter veins (16-18).

In this study, RFA showed clear had advantages during the intervention follow-up period. After 24 hours, no cases demonstrated ecchymosis and the mean VAS value reported by the RFA group was significantly lower than that reported by the LA group. Moreover, the complication rate for the RFA group was also lower than that for the LA group. In the LA group, the adverse event risk was greater than that in the RFA group, which may be due to the increased severity of lesions and associated aneurysms. Theoretically, the superiority of RFA may be attributed to the impacts of RFA on the venous wall collagen layer. Furthermore, overall temperature regulation was maintained at 120°C during the RFA procedure, which may prevent adverse impacts on surrounding tissues. In contrast, LA causes a rapid increase in temperature and reaches the optimum temperature based on the catheter revocation rate. LA function is based on the extremely hot carbonized coating covering the tip of the fiber that will heat up the blood exposed to the tip of the fiber through direct laser light absorption. The occurrence rates of adverse events related to LA therapy, such as paresthesia, numbness, and hyperpigmentation, observed in this study were similar to those reported by previous studies (15-18). However, these typical side effects were generally mild, and no further treatments were required.

The current study has some limitations. First, it would be an uncontrolled bias due to the limited sample size and the retrospective, single-center nature of this study. The number of patients in RFA group was relatively small in comparison with that in LA group. Hence, future studies will be necessary to confirm our results, using a prospective multicenter design with a larger scale. Second, the follow-up time for this analysis was only 1 month. A longer follow-up duration should be examined to determine the effectiveness of all ablation approaches after at least 6 to 12 months.

6. CONCLUSION

In general, LA and RFA were minimally invasive and safe therapies for CVI in the lower extremities. No severe complications were observed that required further interventions. Clinical symptoms were resolved effectively. Based on our findings, we propose that RFA should be used to treat small, dilated saphenous veins, whereas LA should be used to treat broad, dilated saphenous veins, either with or without aneurysms.

- **Ethical approval and Declaration of patient consent**: Institutional review board of Bach Mai hospital approved this study. Informed consent of patients was obtained.
- **Author's contribution**: Nguyen Minh Duc and Tran Anh Tuan gave a substantial contribution in acquisition, analysis, and data interpretation. Nguyen Minh Duc and Le Nguyet Minh prepared, drafted, and revised manuscript critically for important intellectual content. Each author gave the final approval of the version to be published and agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- **Conflicts of interest**: There are no conflicts of interest to declare.
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