Comparison of Short-Term Outcomes between Endovenous 1940 nm Laser Ablation and Radiofrequency Ablation for Incompetent Saphenous Veins

Insoo Park1 and Sun-Cheol Park2*

1Charm Vascular Clinic, Nambusunhwan-ro, Seoul, Republic of Korea
2Department of Surgery, Division of Vascular and Transplant Surgery, College of Medicine, The Catholic University of Korea, Seoul, Republic of Korea

Abstract

Background: Radiofrequency Ablation (RFA) has shown faster recovery and lower pain scores compared to Endovenous Laser Ablation (EVLA) for treatment of varicose veins. However, a comparison of 1940 nm EVLA and RFA has not been reported. This study compared short-term outcomes using 1940 nm EVLA and RFA for varicose veins.

Methods: Between April 2018 and June 2018, 43 patients (83 incompetent saphenous veins) were treated with 1940 nm EVLA and 37 patients (64 incompetent saphenous veins) with RFA. Follow-up duplex was checked at 1 month and 3 months.

Results: Baseline characteristics showed no significant differences between both groups except for age. Pain scores at 6 h, and at 1, 10, and 30 days after treatment showed no differences. Complications and time to return to normal activity showed no differences. The 100% closure rate was checked in both groups at 1 month and 3 months follow-up.

Conclusion: Short-term outcomes showed no significant differences between 1940 nm EVLA and RFA treatment.

Keywords: Varicose veins; Endovenous laser ablation; Radiofrequency ablation; RFA; 1940 nm
Material and Methods

Patients

A total of 115 patients who underwent RFA or EVLA at the Charm Vascular Clinic between April 2018 and July 2018 were enrolled in this study. All patients were provided an explanation of the study and gave informed consent. Ethical approval was gained from the Institutional Review Board of The Catholic University of Korea, Seoul St. Mary’s Hospital (No. KC19RESI0138). This is a retrospective comparative study.

All targeted veins for treatment demonstrated at least 0.5 s of reflux and a diameter of ≥ 3 mm at 3 cm distal to the Saphenofemoral Junction (SFJ) in standing position.

The exclusion criteria were as follows: 1) diameter of the treated vein >12 mm, 2) length of epifascial saphenous vein >10 cm, 3) number of concomitant phlebectomies >20, 4) recurrent varicose vein, or 5) patient refusal to participate. Thirty-five patients were excluded, resulting in 80 patients included in the study.

The preoperative Clinical, Etiologic, Anatomic, Pathophysiologic (CEAP) grades were C1-C5 (C1: telangiectasia or reticular veins, C2: varicose veins, C3: edema, C4a: pigmentation or eczema, C4b: lipodermatosclerosis or atrophic Blanche, C5: healed ulcer). We classified the patients as per highest clinical grade of the two limbs. 3 patients with C1 grade were included due to symptoms such as aching, cramping, heaviness, and tingling.

The Revised Venous Clinical Severity Score (RVCSS) and Aberdeen Varicose Vein Questionnaires (AVVQ) were determined before treatment. We determined patients as per highest RVCSS of the two limbs. Post-treatment pain was assessed with the numerical pain rating scale (NRS; 0-10), and the number of days until return to normal activity was determined. Duplex sonograms were performed at 1 month and 3 months after treatment. All procedures were performed by one surgeon who has treated >500 cases each with EVLA and RFA.

EVLA

For EVLA, access was gained using a 16-G angio needle, and a ball-tip fiber (CareTech, Sung-nam, Korea) was directly inserted into the 16-G needle without using an introducer sheath or guide. An about 5 cm length of initial ablation area was manually compressed during ablation, and compression was not applied below this area. Power and manual pull-back speed were mostly set to 6 W and 0.10 cm/sec to 0.15 cm/sec, and did not get out of the 3 W to 6 W and 0.1 cm/sec to 0.2 cm/sec ranges. Speed for the proximal area near the junction was maintained at 0.10 cm/s; when vein diameter decreased as the fiber moved downward, the pull-back speed was elevated at the surgeon’s discretion.

RFA

RFA was performed using the Closure Fast catheter (VNUS Medical Technologies, San Jose, CA, USA) according to the manufacturer’s instructions. Access was gained using a 7-Fr introductor sheath (Terumo, RADIOFOCUS INTRODUCER II Fr. 7, Japan). The first proximal segment was treated with double-cycle ablation, and single-cycle ablation was applied to areas below this segment. Manual compression was performed above the veins throughout the ablation.

After completing the above procedures, concomitant phlebectomy or sclerotherapy was performed for a branching varix or reticular vein/telangiectasia at the surgeon’s discretion. Patients were discharged on the same day, about 4 h to 8 h after the procedure, and were advised to ambulate. As post-procedural medication, oral non-steroidal anti-inflammatory drugs were taken for 3 days, and patients were advised to wear thigh-level 20 mmHg to 30 mmHg compressive stockings for 2 weeks during the day time. Thromboprophylaxis medications were not prescribed. Pain score (NRS) was measured at 6 h, and at 1, 10, and 30 days after procedure. The number of days until return to normal activity was surveyed over the phone at 1 week after treatment. Sonogram follow-up was performed at 1 month and 3 months after treatment. Complications were assessed during the 1-month follow-up period.

Statistical analysis

All data are presented as mean ± standard deviation. A two-tailed Student t-test was used to calculate statistical significance for differences in continuous variables. A Fisher exact test or chi-square test was used to evaluate differences in categorical variables.

Table 1: Patient demographics mean (± SD), range, or number (%).

|                  | EVLA (n=43) | RFA (n=37) | p-value |
|------------------|-------------|------------|---------|
| Female           | 30 (69.8%)  | 25 (67.6%) | 0.227   |
| Age              | 47.4 ± 13.8 | 40.4 ± 14.3| 0.03    |
| BMI              | 22.7 ± 3.4  | 23.2 ± 3.4 | 0.539   |
| CEAP             |             |            | 0.609   |
| C1               | 2           | 1          |         |
| C2               | 19          | 17         |         |
| C3               | 19          | 16         |         |
| C4               | 3           | 3          |         |
| C5               | -           | 1          |         |
| No of treated veins/patient | 1.95 ± 0.75 | 1.76 ± 0.79 | 0.262   |
| Initial RVCSS    | 5.0 ± 1.4   | 4.7 ± 1.7  | 0.365   |
| Initial AVVQ     | 14.8 ± 7.6  | 12.7 ± 5.9 | 0.193   |

EVLA: Endovenous Laser Ablation; RFA: Radiofrequency Ablation; BMI: Body Mass Index (kg/m^2); CEAP: Clinical, Etiologic, Anatomic, Pathophysiologic class; RVCSS: Revised Venous Clinical Severity Score; AVVQ: Aberdeen Varicose Vein Questionnaires
Sun-Cheol Park, et al., Clinics in Surgery - Vascular Surgery

Thrombosis
Endovenous Heat Induced Thrombosis (Kabnick classification); DVT: Deep Vein Thrombophlebitis:

**Table 4:** Duplex sonogram at 1 month and 3 months.

| EVLA (n=83) | RFA (n=64) | p-value |
|------------|------------|---------|
| 1 month    | 3 months   | 1 month | 3 months |
| Follow-up rate | 79/83 (95.2%) | 49/83 (59.0%) | 63/64 (98.4%) | 30/64 (46.9%) | - |
| Anatomical success rate | 79/79 (100%) | 49/49 | 62/63* (98.4%) | 30/30 | 0.261 |
| Reflux free rate | 79/79 (100%) | 49/49 | 63/63 | 30/30 | - |

Definition of anatomical success: Any color flow in treated area <3 cm. 1 GSV showed color flow without reflux after RFA at 1 month. *Definition of reflux: Any reflux flow in treated area >3 cm

The 2 groups did not significantly differ in complications; there was 1 case of endovenous heat-induced thrombosis (EHIT) in the EVLA group (Table 4). Which was Kabnick classification 1 in SSV.

Duplex sonograms performed 1 month and 3 months after the procedure confirmed that both groups were 100% reflux free rate (Table 5).

**Discussion**

In the present study, the 1940 nm EVLA group and RFA group did not significantly differ in postoperative pain, recovery time, complications, 1 month and 3 months closure rate.

According to previous literatures, the required energy for good outcomes is about 80 to 100 LEED (J/cm) with the 1470 nm EVLA [11,13,14]. And to date, a few studies have investigated EVLA using the 1940 nm laser, and this treatment has generally produced good outcomes, even with energy <50 LEED (J/cm) [19-24]. Absorption at particular chromophore and absorption coefficients differ according to laser wavelength. At lower wavelengths (800 nm to 900 nm), the absorption coefficient for hemoglobin was higher than that for water. On the other hand, with introduction of water-specific, higher wavelengths, the chromophore changed from hemoglobin to water in vein walls. Thus, it is now theoretically possible to efficiently treat vein walls with lower power than before, with lasers of higher wavelengths [11,12].

In the 2000s, when the Closure Fast system was introduced, studies found that RFA caused less postoperative pain and bruising with quicker recovery compared to treatment using lower wavelengths of 810 nm or 980 nm [6-10]. However, since the introduction of laser of a higher wavelength, recent several studies, including a prospective 5 years study, reported that 1470 nm EVLA using a radial fiber was associated with similar outcomes or even less postoperative pain and shorter recovery time compared to RFA [15-18].

We used a ball-tip fiber in this study because radial fibers produced in Korea had some shortcomings during the study period. Using a radial fiber reduces perforation caused by direct contact and leads to efficient circumferential thermal damage, which enables effective treatment at lower power. Thus, we could predict that post-procedural pain would be less than when a bare-tip fiber or ball-tip fiber was used [6]. In the future, we will expect to report outcomes with 1940 nm EVLA when a radial fiber is used.

This study was limited by the non-randomized, single-center setting and relatively small sample of subjects. Moreover, only the short-term post-procedural results were analyzed. Further investigation should evaluate this in future.
Conclusion
This study is the first comparative study between 1940 nm EVLA and RFA. And the short-term outcomes between both groups showed no difference in pain score, recovery time, complications, 1 month and 3 months closure rate. Larger and more long-term randomized studies are needed.

References
1. Giovacchini P, Comerota A, Dalsing M, Eklöf BG, Gillespie DL, Giovacchini ML, et al. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011;53(5 Suppl):2S-48S.
2. Marsden G, Perry MC, Kelly K, Davies AH. Diagnosis and management of varicose veins in the leg: Summary of NICE guidance. BMJ. 2013;347:f4279.
3. Venous Forum of the Royal Society of Medicine; Bertridge D, Bradbury AW, Davies AH, Golmohamed M, Nyamekeye I, et al. Recommendations for the referral and treatment of patients with lower limb chronic venous insufficiency (including varicose veins). Phlebology. 2011;26(3):91-3.
4. Siribumrungwong B, Noort P, Wilsaarsme C, Atta J, Thakkinistian A. A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein. Eur J Vasc Endovasc Surg. 2012;44(2):214-23.
5. Brar R, Nordon IM, Hinchliffe RJ, Loftus IM, Thompson MM. Surgical management of varicose veins: Meta-analysis. Vascular. 2010;18(4):205-20.
6. Shepherd AC, Gohel MS, Brown LC, Metcalfe MJ, Hamish M, Davies AH. Randomized clinical trial of VNUS ClosureFAST radiofrequency ablation versus laser ablation for varicose veins. Br J Surg. 2010;97(6):810-8.
7. Almeida JL, Kaufman J, Göckeritz O, Chopra P, Evans MT, Hoheim DF, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: A multicenter, single-blinded, randomized study (RECOVERY study). J Vasc Interv Radiol. 2009;20(6):752-9.
8. Goode SD, Chowdhury A, Crockett M, Beech A, Simpson R, Richards T, et al. Laser and radiofrequency ablation study (LARA study): A randomised study comparing radiofrequency ablation and endovenous laser closure (810 nm). Eur J Vasc Endovasc Surg. 2010;40(2):246-53.
9. Krmč A, Sušić Z. Bipolar radiofrequency induced thermotherapy and 1064 nm Nd:Yag laser in endovenous occlusion of insufficient veins: Short term follow up results. Vasa. 2011;40(3):235-40.
10. Nordon IM, Hinchliffe RJ, Brar R, Moxey P, Black SA, Thompson MM, et al. A prospective double-blind randomized controlled trial of radiofrequency thermal treatment of the great saphenous vein in patients with varicose veins. Ann Surg. 2011;254(6):876-81.
11. Cowpland CA, Cleese AL, Whiteley MS. Factors affecting optimal linear endovenous energy density for endovenous laser ablation in incompetent lower limb truncal veins - A review of the clinical evidence. Phlebology. 2017;32(5):299-306.
12. Martin van Gemert JC, Cees van der Geld WM, Cornelis Bruijininkx MA, Rudolf Verdaasdonk M, Martino Neumann HA. Comment to Vuylsteke ME and Mordon SR. Endovenous laser ablation: A review of mechanisms of action. Ann Vasc Surg. 2012;26:881-3.
13. Schwarz T, von Hodenberg E, Furtwangler C, Rastan A, Zeller T, Neumann FJ. Endovenous laser ablation of varicose veins with the 1470-nm diode laser. J Vasc Surg. 2010;51(6):1474-8.
14. von Hodenberg E, Zerweck C, Knittel M, Zeller T, Schwarz T. Endovenous laser ablation of varicose veins with the 1470 nm diode laser using a radial fiber - 1-year follow-up. Phlebology. 2015;30(2):86-90.
15. Lawson J, Gauw SA, van Vlijmen CJ, Pronk P, Gaastma TR, Tangelder MJ, et al. Prospective comparative cohort study evaluating incompetent great saphenous vein closure using radiofrequency-powered segmental ablation or 1470-nm endovenous laser ablation with radial-tip fibers (Varico 2 study). J Vasc Surg: Ven Lymph Dis. 2018;6(1):31-40.
16. Yümkân HN, Gürr Ö, Gürrkan S. Comparison of 1470 nm Radial fiber laser ablation and radiofrequency ablation in endovascular treatment of varous veins insufficiency. W J Cardiovasc Surg. 2016;6(9):117-24.
17. Torma N, Sihotsky V, Kopolovtsev I. A comparison of 1470-nm endovenous laser ablation and radiofrequency ablation in the treatment of great and small saphenous vein insufficiency. J Vasc Surg. 2018;68:e127-8.
18. Mese B, Bozoglu O, Erdem K, Acipayam M, Ekerbicer HC, et al. A comparison of 1,470-nm endovenous laser ablation and radiofrequency ablation in the treatment of great saphenous veins 10 mm or more in size. Ann Vasc Surg. 2015;29(7):1368-72.
19. Schmedt CG, Espisova A, Dikic S, Setia A, Demhasas S, Dieckmann T, et al. Endovenous Laser Therapy (ELT) of saphenous vein reflux using thulium laser (Tm, 1400 nm) with radial fiber - One year results. Eur J Vasc Endovasc Surg. 2016;52:413-4.
20. Sroka R, Pongratz T, Espisova A, Dikic S, Demhasas S, Comsa F, et al. Endovenous laser therapy for occlusion of incompetent saphenous veins using 1940 nm. In: LiGe L, Sroka R, editors. Medical laser applications and laser-tissue interactions. 7th ed. SPIE Proceedings. 2015;95420D.
21. Mendes-Pinto D, Bastianetto P, Cavalcanti Braga Lyra L, Kikuchi R, Kabnick L. Endovenous laser ablation of varicose veins comparing 1920-nm and 1470-nm diode laser. Int Angiol. 2016;35(6):599-604.
22. Viarenago LM, Viarenago G, Martins AM, Mancini MW, Lopes LA. Medium and long-term outcomes of endovenous treatment of varicose veins with a 1940 nm diode laser: Critical analysis and technical considerations. J Vasc Bras. 2017;16:23-30.
23. Park I. Initial outcomes of endovenous laser ablation with 1940 nm diode laser in the treatment of incompetent saphenous veins. Vascular. 2019;27:27-32.
24. Amamoto T, Sakata M. Influence of fibers and wavelengths on the mechanism of action of endovenous laser ablation. J Vasc Surg Venous Lymphat Disord. 2014;2(1):61-69.