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Outcomes of endovenous laser ablation using a 1470-nm laser for the treatment of incompetent great saphenous veins: Real-world data

Tran Duc Hung [1,*], Vu Minh Phuc [1], Do Van Chien [2]
[1]Cardiology Centre, 103 Military Hospital, Hanoi, Vietnam
[2]Heart Institute, 108 Military Central Hospital, Hanoi, Vietnam

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Abstract

This study aimed to show outcomes and side effects after endovenous laser ablation of incompetent great saphenous veins (GSV) with a 1470 nm Diode laser under real-world conditions. A before-after observational study was conducted on 814 patients (1089 lower limbs) with GSV who underwent endovenous laser ablation using 1470 nm from July 2016 to November 2022 at Cardiology Center, Military Hospital 103. The patients were assessed for disease severity using clinical, etiological, anatomical and pathological (CEAP) scores and venous clinical severity scores (VCSS). The Chronic Venous Insufficiency Quality of Life Questionnaire 20 (CIVIQ-20) pre- and post-operatively measured the quality of life. Patient-reported outcome measures were collected at follow-up one month after discharge. 814 cases with a mean age of 59.60 ± 13.49 years were studied (61.8% female). One month after laser ablation, patients with a CEAP clinical class C2 decreased significantly compared to the before (15.5% versus 52.3%; p <0.01, respectively). None of the patients with class C3 and C6 were observed. The VCSS and CIVIQ-20 scores after laser treatment decreased significantly compared to before (2.74 ± 1.79 versus 6.70 ± 2.37 and 24.59 ± 3.05 versus 35.90 ± 8.95; p <0.01). The common complications were ecchymoses (34.2%), induration (9.1%), dysesthesia (0.5%) and deep vein thrombosis (DVT) (0.1%). Endovenous laser ablation effectively improves clinical symptoms and quality of life in patients with GSV incompetence. It is a valid, minimally invasive procedure for treating GSV incompetence with minimal complications and a short recovery period.

Keywords: 1470 nm laser treatment, incompetent great saphenous veins, endovenous laser ablation, CIVIQ-20

1. Introduction

Chronic venous insufficiency (CVI) refers to a collection of clinical symptoms resulting from hemodynamic abnormalities, specifically reflux and obstruction, in the peripheral venous system, typically affecting the lower extremities (1). The occurrence of CVI around the world ranges from less than 1% to 17% in men and less than 1% to 40% in women (2). The differences in these ranges are probably due to variations in how diagnostic criteria are applied, the access to medical resources for diagnosis and treatment, and the distribution of risk factors that are specific to different populations around the world (2). Worldwide, 1-2% of adults have lower limb ulcers, rising to 3% for individuals aged 65 years and older. It is believed that the incidence of CVI is more significant in Western European countries, the United States, and other developed nations, possibly as a result of lifestyle choices and sedentary behavior (1).

Superficial lower limb venous insufficiency encompasses insufficiencies of both the greater and small saphenous insufficiency. The incidence of incompetent great saphenous veins (GSV) is notably high, with over 90% of cases being attributed to this condition (3). The clinical examination may reveal signs of dilated reticular veins, mesh-like veins, dilated varicose veins, oedema, changes in skin pigmentation, dermatitis, and ulceration. The treatment requires long-term duration and the integration of multiple approaches (1).

In the severe stage of the incompetent GSV, it is necessary to eliminate the refluxing vein through surgery or endovenous thermal ablation (using radiofrequency or laser energy) to destroy the diseased veins irreversibly (4). In the past, the standard treatment method was surgical tightening or removal of visibly enlarged veins. However, surgical procedures have some drawbacks, such as excessive bleeding, infection, inflammation of the veins, nerve damage, and leaving scars that may affect the patient's aesthetics (5). Meanwhile, the use of 1470 nm laser treatment for venous insufficiency has been proven to be as effective as surgery, with the advantages of minimally invasive procedure, quick procedure times, only requiring local anaesthesia with fast recovery time (6, 7). This study showed outcomes and side effects after endovenous laser ablation of incompetent GSV with a 1470 nm Diode laser under real-world conditions.

2. Material and Methods

2.1. Study design and patients

A before-after observational study was conducted on 814 patients (1089 lower limbs) with incompetent GSV who underwent endovenous laser ablation using 1470 nm from July 2016 to November 2022 at Cardiology Center, Military Hospital 103. The selection criteria include 1) Patients with

*Correspondence: dovanchien108.cmh@gmail.com

symptoms of lower extremity venous insufficiency, reflux time in the GSV measured by Doppler ultrasound exceeding 0.5 seconds (6); 2) Patients with symptoms of chronic venous insufficiency in the lower extremities, CEAP clinical class C2 to C6, showing poor response to conservative treatment, indicated for endovenous laser therapy, and 3) Patient's willingness to undergo intervention. The exclusion criteria encompass patients with small saphenous vein (SSV) incompetence, DVT, severe systemic illness, immobility, localised infection at the venous access site, and unwillingness to undergo surgery. The protocol for this study received approval from the Institutional Review Board of Military Hospital 103.

2.2. Study procedure

The patient underwent a clinical examination and was prescribed a lower limb venous ultrasound. Afterwards, they were assessed for disease severity using clinical, etiological, anatomical and pathological (CEAP) scores and venous clinical severity scores (VCSS). The Chronic Venous Insufficiency Quality of Life Questionnaire 20 (CIVIQ-20) pre- and post-operatively measured the quality of life.

The patients were treated with endovenous laser ablation using the Venacure machine equipped with a Nerver touch tip operating at a wavelength of 1470 nm from Angiodynamic (United States). Patient-reported outcome measures were collected at follow-up one month after discharge.

The diagnosis criteria for venous insufficiency were based on the European Society for Vascular Surgery standards in 2015 (2). Successful treatment was achieved when the GSV was treated for sclerosis, completely blocked, and confirmed by ultrasound.

2.3. Statistical analysis

The paired-sample t-test was employed for statistical analysis to compare the before and after treatment. A $\chi 2$ test was used to compare the frequency or magnitude of change before and after treatment. A p-value less than 0.05 was considered to be statistically significant.

3. Results

Table 1 illustrates that, out of a total of 814 patients, the mean age of the study group was 59.60 ± 13.49 years (range 22-84 years). The proportion of females (61.8%) was higher than that of males (38.2%). Patients in clinical stage C2 had the highest proportion (52.3%), while stages C5 and C6 had lower proportions (2.5%, respectively). The occurrence rate of single limb injury in patients was higher than that of dual limb injury. The mean diameter of the GSV before treatment was 6.51 (SD=1.66) mm (range 3.6-11.8 mm). The average energy density per unit length was 66.21 J/cm (SD=13.09) (range 30.00-104.4 J/cm).

Table 1. Clinical characteristics of patients and characteristics of energy density for treatment

Characteristics	Value
Age, years, Mean (SD)	59.60 (13.49)
Gender, Female, n(%)	503 (61.8%)
Clinical classification	
C0: No visible venous diseases	0 (0.0%)
C1: Telangiectatic or reticular veins	0 (0.0%)
C2: Varicose veins	425 (52.3%)
C3: Varicose veins with oedema	240 (29.5%)
C4: Varicose veins with skin changes without ulcer	128 (15.7%)
C5 & C6: Varicose veins with skin changes and healed/active ulcer	21 (2.5%)
Position of injury	
Single limb injury	539 (66.2%)
Dual limb injury	275 (33.8%)
Energy density, J/cm, Mean(SD)	66.21 (13.09)
Great saphenous vein diameter, mm, Mean(SD)	6.51 (1.66)

Table 2 indicates that after intervention, the proportion of patients in stage C1 significantly increased (66.3%), while the rate of patients in stage C2 decreased remarkably compared to that before intervention (15.5% versus 52.3%; $p < 0.01$, respectively). After intervention, none of the patients were in the C3 and C6 stages. The mean VCSS score after the intervention decreased significantly compared to before the intervention (2.74 ± 1.79 versus 6.70 ± 2.37; $p < 0.01$, respectively). The post-intervention CIVIQ-20 scores demonstrated a statistically significant reduction compared to pre-intervention scores (24.59 ± 3.05 vs 35.90 ± 8.95; $p < 0.01$).

Table 2. Clinical classification, clinical severity and quality of life before and after treatment

Characteristics	Before	After	P-value
	N(%)	N(%)	
C0: No visible venous diseases	0 (0.0%)	0 (0.0%)	<0.01
C1: Telangiectatic or reticular veins	0 (0.0%)	540 (66.3%)	
C2: Varicose veins	425 (52.3%)	125 (15.5%)	
C3: Varicose veins with oedema	240 (29.5%)	0 (0.0%)	
C4: Varicose veins with skin changes without ulcer	128 (15.7%)	128 (15.7%)	
C5: Varicose veins with skin changes and healed ulcer	19 (2.3%)	21 (2.5%)	
C6: Varicose veins with skin changes and active ulcer	2 (0.2%)	0 (0.0%)	
	Mean (SD)	Mean (SD)	
VCSS score	6.70 (2.37)	2.74 (1.79)	<0.01
CIVI20 score	35.90 (8.95)	24.59 (3.05)	<0.01

* Abbrev: CIVIQ20: Chronic Venous Insufficiency Questionnaire-20 item; VCSS: Venous Clinical Severity Score

Table 3 shows the complete patency rate of the venous system after one month of treatment to be 99.96%. The mean postoperative pain duration is 12.42 (SD=3.30) days, and the time to return to normal activities was 1.80 (SD=0.87) days. The common complications were ecchymoses (34.2%), induration (9.1%), dysesthesia (0.5%) and deep vein thrombosis (0.1%). Fig. 1 illustrates a patient's outcome before and one week after endovenous laser ablation of the GSV.

Table 3. Outcomes of treatment

Characteristics (n=814)	Value
Pain time after procedure, days, Mean (SD)	12.42 (3.30)
Time to return to daily activities, days, Mean (SD)	1.78 (0.80)
Success rate	813 (99.96%)
Recanalisation rate after one month	1 (0.04%)
Complication, n(%) (n=1089)	
Deep vein thrombosis	1 (0.1%)
Infection	1 (0.1%)
Ecchymoses	372 (34.2%)
Induration	99 (9.1%)
Dysesthesia	5 (0.5%)

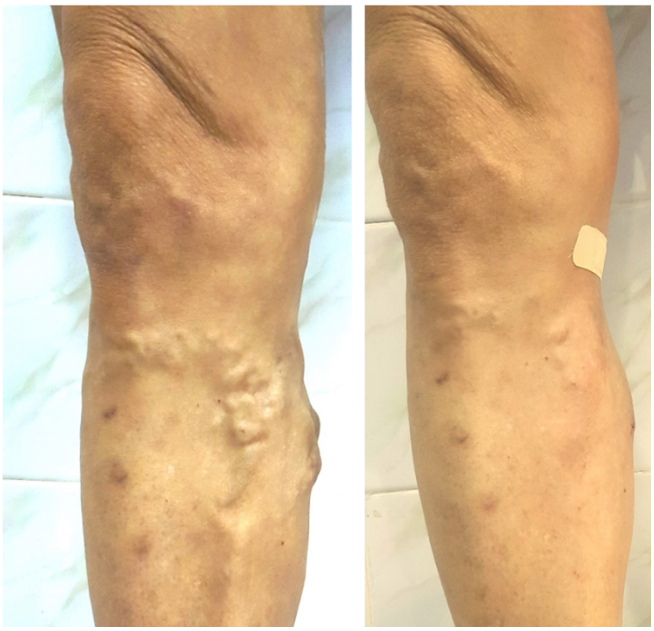

Fig. 1. 72 y/o male before and 1 week after endovenous laser ablation of the GSV

4. Discussion

The application of a 1470-nm diode laser has exhibited favorable efficacy in the management of pronounced saphenous insufficiency. The efficacy of 1470-nm lasers in the management of greater saphenous insufficiency is ascribed to their elevated specific absorption by water in comparison to the lower wavelength lasers (980 nm) previously employed (8). The wavelength specific to water enables a more precise targeting of the vein wall by selectively absorbing interstitial water, thereby leading to more efficient damage to the diseased veins (8). Furthermore, there is evidence suggesting that tissue penetration depth is inversely correlated with increasing wavelength, resulting in reduced rates of vein wall perforation and ecchymosis when using 1470-nm lasers. As a result, medical practitioners have shown a preference for 1470-nm lasers over lower haemoglobin-specific wavelength lasers when treating saphenous vein incompetence, citing the advantages associated with the former (9).

All patients in the study were indicated for laser treatment for varicose veins, with the clinical stage ranging from C2 to C6. The clinical stage C2 accounted for a high proportion (52.2%), while the severe stages, such as C5 and C6, accounted for meagre proportions (2.3% and 0.2%, respectively). The results were in line with previous research. Nada et al. revealed that C2 was the most common stage, making up 62.55% of cases, with C3, C4, and C5 stages following at 15.6%, 15.6%, and 6.25%, respectively (10). A different research study revealed that among patients with chronic venous insufficiency, 143 limbs were classified as C2, five were categorised as C3, 12 as C4, two as C5, and nine as C6 11). The intervention can significantly reduce the percentage of patients in stage C1, from 66.3% to 15.5%, while eliminating patients in stage C2. This shows a significant improvement in clinical outcomes following the intervention. Due to the unchanged areas of calloused skin and old scars, patients in stages C4 and C5 do not experience a change in clinical classification.

Identifying the optimal energy density is crucial in achieving treatment goals, minimising damage to surrounding tissues, and reducing the recurrence rate (9). According to Park (2014), an energy density level between 53.3 and 80 J/cm, with an average of 72.4 J/cm, is sufficient to achieve the treatment goal (11). However, according to Malskat, there is no significant difference in the complete obstruction rate of treated greater saphenous insufficiency between LEED levels of < 50 J/cm and > 50 J/cm (12). In our study, the average LEED was 66. 21 ± 1309 J/cm, with the highest at 104.50 J/cm and the lowest at 30.00. In Ferreira's study, the achieved therapeutic goal was a significant energy density level of 46.86 J/cm for the great saphenous vein. The differences in types of laser heads lead to variations in energy delivery within the vein and burning length, which can result in different levels of LEED among studies (13).

The success rate of treatment after one month was 99.96%, which serves as the benchmark for evaluating the procedure's success. Other studies have also demonstrated a high success rate, such as the research conducted by Karathanos (2021), which reported a success rate of 95% (6). The average postoperative pain duration was 12.42 ± 3.30 days, predominantly characterised by mild intensity and does not significantly impact normal activities. Patients typically require an average of 1.78 ± 0.80 days to return to their daily activities. According to Venermo, the use of endovascular laser therapy significantly reduces post-treatment pain duration when compared to surgical intervention, with average pain duration of 8 days (14). The research conducted by Rasmussen

indicates that, on average, patients require a period of two days to return to their normal activities (5).

Our study observed an improvement in clinical symptoms following treatment as measured by the VCSS scale. There was a statistically significant decrease in VCSS score after treatment (2.74 ± 179) compared to before treatment (6.70 ± 237); p < 0. 001. The study conducted by Karathanos (2021) demonstrates a significant reduction in VCSS following intervention compared to pre-intervention levels (6.6 ± 2.8 versus 4.9 ± 2.2) (6). Regarding quality of life, as measured by the CIVIQ-20 scale, the pre-intervention assessment score (35.90 ± 8.95) significantly decreased to (24.59 ± 3.05) after one month of treatment. The findings of our study are consistent with those of Vourliotakis (2018), who demonstrated a reduction in CIVIQ-20 score from 77.0 ± 3.9 to 36.3 ± 3.0 following intervention (15). Numerous studies consistently demonstrate significant improvement in patients' quality of life following endovascular laser treatment (16).

A comprehensive review of literature pertaining to endovenous laser therapy revealed that the prevailing complications were ecchymoses and pain, with or without induration, occurring in 100% of cases. Additionally, the incidence of skin burns was reported in 0-1% of cases, dysesthesia in 0-22%, superficial thrombophlebitis in 0-25%, DVT in 0-6%, nerve injury in 0-1%, and hematoma occurred less frequently. There is considerable variation in the reported frequencies across different studies (17). The common complications of our research were ecchymoses (34.2%), induration (9.1%), and dysesthesia (0.5%). Most adverse events associated with endovenous laser therapy were minor complications, except asymptomatic DVT, which occurs in 0.1% of patients. DVT can be an extension of a thrombus from the treated truncal vein across the junctional connection into the deep vein or the calf or femoral, popliteal veins. Most series using early duplex ultrasound (72 h after laser therapy) document a proximal extension for the great saphenous vein of approximately 1% (This type of DVT is almost universally asymptomatic. (18).

Our study had a strength in a large sample size of patients with greater saphenous insufficiency. However, this study had limitations in using a before-after design without a control group. Moreover, our study was only performed in one medical center, which limit the ability to generalise to patients in other hospitals.

Endovenous laser ablation effectively improves clinical symptoms and quality of life in patients with GSV incompetence. It is a valid, minimally invasive procedure for treating GSV incompetence with minimal complications and a short recovery period.

Conflict of interest

The authors declared no conflict of interest.

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None to declare.

Authors' contributions

Concept: T.D.H., D.V.C., Design: T.D.H., D.V.C., Data Collection or Processing: T.D.H., V.M.P., Analysis or Interpretation: T.D.H., D.V.C., Literature Search: T.D.H., D.V.C., V.M.P. Writing: T.D.H., D.V.C., V.M.P.

Ethical Statement

Approval was obtained from The Biomedical Research Ethics Council-103 Military Hospital, the study started. The ethics committee decision date is 09/01/2020 and the number of ethical committee decisions is 219/QD-HVQY.

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