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Original Article

Evaluating endovenous laser and glue ablation in the treatment of great saphenous vein insufficiency: A 5-year retrospective comparative study

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Abstract

Aim: The use of endovascular thermal and nonthermal methods in the treatment of chronic venous insufficiency has been in practice for over 10 years. The early results of these practices have been published and extensively discussed. Medium and long-term results are now being announced. In our study, we discussed the results of endovenous laser ablation and endovenous glue ablation methods, along with hemodynamic evaluations.

Material and Methods: Doppler USG and Digital Photo Plethysmography were used to examine patients with chronic venous insufficiency in the C2-5 group who received endovenous ablation indication. Records of VCSS and CIVIQ-20 were obtained. Measurements were taken at 1, 3, 6, 12, 24, and 60 months. Procedural and post-procedural variables were compared, and the results were obtained for a 5-year period.

Results: The demographic profiles of the groups were similar. The duration of the procedure was significantly longer in the EVLA group. Similarly, the pain during the procedure was statistically significantly higher in the EVLA group. Venous refill time and venous half-life time showed a statistically significant improvement in both groups. While there were close to 100% closure rates in both groups during the first 6 months, the rates decreased to 95.2% in EVLA and 93.5% in EVGA by the end of the fifth year.

Conclusion: With 5 years of objective and subjective findings, both EVLA and EVGA are effective and reliable methods with their advantages and disadvantages. However, EVGA may be more preferred by patients because it does not require tumescent anesthesia, causes less pain, and has a shorter procedure time.

Keywords: Endovenous laser ablation, endovenous glue ablation, plethysmography, chronic venous insufficiency

INTRODUCTION

Treatment of chronic venous insufficiency (CVI) has been a topic of concern for vascular surgeons for many years. They strive to promptly and effectively address the patients' complaints, aiming to provide the most comfortable and long-lasting solution. The reason for this is that CVI is prevalent in large segments of society, negatively impacting the quality of life and potentially

leading to irreversible damage if left untreated [1].

In recent years, thermal (laser, radiofrequency, steam) and nonthermal (glue, mechanochemical) endovenous techniques that closely align with these ideals have been frequently utilized [2]. Among them, endovenous laser ablation (EVLA) and endovenous glue ablation (EVGA) stand out [3-5].

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Although these new techniques provide benefits such as reduced invasiveness, decreased postoperative pain, and shorter recovery time, they also have some differences among them. The most important distinction is that while EVLA generates high heat using light energy, EVGA cyanoacrylate relies on the chemical damage effect and does not produce high temperatures [3]. Therefore, while performing EVLA, tumescent anesthesia is required, while EVGA does not require anesthesia in order to avoid tissue damage caused by high heat [6]. Despite the use of tumescent anesthesia, high heat during EVLA can lead to vein disintegration or cause paresthesia due to nerve damage [7,8].

Cyanoacrylate is a substance that, when applied, rapidly polymerizes into a tissue adhesive, effectively occluding veins. It has been safely used in the treatment of arteriovenous malformation, esophagogastric varices, and oral surgery for approximately 20 years [9-11].

Doppler ultrasound examination and CEAP (the clinical, etiological, anatomical, and pathophysiological classification) are used as objective methods to investigate the efficacy of thermal and nonthermal endovenous treatments. Subjective evaluation is conducted using methods such as VCSS and CIVIQ-20 [12- 15]. However, many studies on venous volume, which is the primary focus of venous pathophysiology, were not included in these evaluations. In this respect, changes in venous volume and venous hemodynamics seem to be overlooked. For this reason, we also used the venous hemodynamic changes obtained by using Digital PhotoPlethysmography (D-PPG) in our evaluation.

In this study, we investigated the 5-year clinical results of EVLA and EVGA methods, accompanied by venous hemodynamic findings that were measured using D-PPG.

MATERIAL AND METHODS

This retrospective study was conducted by examining the 5-year records of 152 consecutive and randomized EVLA patients and 133 EVGA patients from 2015 to 2018. A total of 285 patients who met the inclusion criteria were enrolled in the study. Inclusion and exclusion criteria are detailed in Table 1. Additionally, all patients signed an informed consent form. Data analysis was conducted after obtaining approval from the Regional Ethics Committee (Uludağ University Research Ethics Committee; decision number 2023-17/26).

Patients who presented to the outpatient clinic with complaints of CVI and were classified under the C2-5 group according to CEAP, and who were indicated for endovenous ablation based on their medical history, examinations, and Doppler ultrasound results, were reviewed retrospectively. Additionally, these patients had their Venous Refill Time (VRT) and Venous Half-Life Time (TH) measured using D-PPG.

Table 1. Inclusion and exclusion criteria

Inclusion criteria

- **1. Age 20 years and 80 years with symptomatic varicose veins**
- **2. CDUS detected reflux of more than 0.5 seconds in the GSV**
- **3. Great saphenous vein (GSV) diameter of more than 5.5 mm**
- **4. CEAP classification of C2–C6**
- **5. Ability to come to follow-up examinations**

Exclusion criteria:

- **2. Duplicate saphenous veins**
- **3. Anterior or posterior accessory saphenous vein varicose**
- **4. Excessive bend in the GSV**
- **5. Femoral or popliteal vein insufficiency**
- **6. Previous deep vein thrombosis**
- **7. Use of warfarin-like oral anticoagulants**
- **8. Peripheral artery disease (ankle brachial index below 0.9)**
- **9. Immobilization**
- **10. Pregnancy**
- **11. Cancer**
- **12. Life expectancy <1 year**

CDUS: Color Doppler Ultrasonography, CEAP: clinical, etiology, anatomy, and pathophysiology classification, GSV: great saphenous vein

Pre-procedural great saphenous vein (GSV) diameters, insufficiency times (measured by Doppler USG while the patient was standing), CEAP classifications, VCSS and CIVIQ-20 records, hemodynamically VRT, and TH measurements of all patients were obtained from the records.

Regarding the procedure, the following factors were recorded: the duration of the procedure, the length of the ablated GSV, the severity of pain during the procedure, and the presence of pain, swelling, bruising, induration, redness, and stiffness after the procedure.

In the follow up, complaints such as long-term deep vein thrombosis, pulmonary embolism, paresthesia, stiffness, and phlebitis were evaluated. VCSS and CIVIQ-20 records were collected, and VRT and TH measurements were conducted on patients who were followed up at 1, 3, 6, 12, 24, and 60 months. All treated vascular segments were classified as recanalized if they exhibited flow on Doppler USG evaluation, as partial if they showed partial flow, and as occluded if they had no flow.

In the plethysmographic study, Digital Photoplethysmography (D-PPG) was used and VRT and TH, which determine the severity of venous insufficiency, were examined. (Plethysmography device; Vasolab 5000, manufacturer ELCAT GmbH, Germany) Data analyzes were provided by Microsoft Windows-based Vasolab 5000 software.

The patient was seated comfortably, reclining on a chair with his legs relaxed and knees bent approximately 110 degrees, and the pelvis plane angle of approximately 110 degrees. Maximum dorsal extensions (maximum toe lift) were performed in sync with the metronome rhythm and with the heel fixed to the ground. Signals were processed by the program via a computer via sensors fixed to the medial calf.

Of the patients who underwent these measurements, which were routinely performed and recorded before and after the procedure in our clinic, a retrospective evaluation was conducted on those who completed the 5-year follow-up.

The EVLA and EVGA procedures, as well as the post-procedure treatment, were performed according to the description provided by Bozkurt et al. [16]. The Evlas® Circular Fiber (Biolas, Ankara, Turkey) was used for EVLA. This fiber operates at a wavelength of 1470nm and was used in conjunction with the 6F introducer kit. The laser fiber is inserted through the introducer kit and advanced until it is 1.5 cm beyond the saphenofemoral junction (SFJ). This ensures that the fiber is properly positioned in the vein. Tumescent anesthesia is administered around the GSV. Thermal laser energy is applied from the SFJ to the access point. The energy density is 10 J/cm/mm with respect to the diameter of the vein.

The VenaBlock® Vascular Closure System (Invamed, Ankara, Turkey) was used for EVGA. The 6F sheath was inserted into the GSV using the Seldinger method, guided by ultrasound (USG). It was confirmed with USG that the tip of the delivery catheter was positioned 1.5 cm proximal to the SFJ. While the catheter was being withdrawn, N-butyl cyanoacrylate (n-BCA) was administered through the catheter using an injection gun. At the same time, pressure was applied to the SFJ with the USG probe and to the GSV with a towel. After the procedure, it was confirmed that the femoral vein was open, and the treated GSV segment was occluded.

For the purpose of evaluating the safety and efficacy of the ablation approach alone, no additional concurrent procedures (such as microphlebectomy or perforator ablation) were conducted. Only microphlebectomy or foam sclerotherapy was used on the remaining side branches three months later, if determined necessary, and records were made.

Statistical Analysis

In the data analysis, IBM SPSS Version 21 and the MedCalc statistical package program were used. Because the Central Limit Theorem allows for compatibility, parametric tests were used without conducting a normality test. However, a non-parametric test was applied to measure VCSS and CIVIQ20, which are ordinal variables. In the analysis of the data, the mean, standard deviation, minimum, and maximum values of the data on the scales were calculated using a continuous structure. Frequency and percentage values were used to describe categorical variables. The Wilcoxon test was used to compare the averages of two repeated measurements for continuous variables. The repeated-ANOVA test statistic was used to compare the means of the seven repeated measurements.

A p-value of less than 0.05 was used to determine statistical significance.

RESULTS

All operational procedures were successfully completed in 285 patients who had indications for endovenous ablation. The demographic profiles of the groups were similar, with no statistically significant differences in terms of patient number, age, or sex. There were also no statistically significant differences in severity of GSV insufficiency and diameters, or CEAP disease stage and in VCSS, CIVIQ-20 score, baseline plethysmographic measurements, VRT, and TH (Table 2).

EVLA: endovenous laser ablation, EVGA: endovenous glue ablation, GSV: great saphenous vein, CEAP: clinical, etiology, anatomy and pathophysiology classification, VCSS: venous clinical severity score, CIVIQ-20: Chronic Venous Insufficiency Quality of Life Questionnaire, VFT: venous refilling time, TH: venous half-value time

The length of the treated segment of the GSV was similar in both groups. The duration of the procedure was significantly longer in the EVLA group $(28.2 \text{ min} \pm 8.5 \text{ vs. } 7 \text{ min} \pm 0.7, \text{ p} < 0.001)$. Similarly, the level of pain experienced during the procedure was statistically significantly higher in the EVLA group $(10.1 \pm 2.2 \text{ vs } 10.1 \pm 1.2)$ 1.5 ± 0.8 , p<0.001) (Table 3).

CA: cyanoacrylate, SD: standard deviation

None of the patients had deep vein thrombosis (DVT) or pulmonary embolism (PE) during or after the procedure. While induration was higher in the EVLA group during the early post-procedure period (22 (14.4%) versus 10 (7.5%), p<0.001), stiffness in the GSV trace was higher in the EVGA group $(3 (2.3\%)$ versus 11 (8.2%) , p<0.001). Indurations were completely resolved at the end of the first month, and stiffness became temporary and not uncomfortable in two patients in the EVGA group. While paresthesia developed in a total of 9 (5.9%) patients - 7 (4.6%) temporary and 2 (1.3%) permanent - in the EVLA group, it was not observed in the EVGA group. Microphlebectomy or foam sclerotherapy was performed on the remaining side branches three months later, if deemed necessary, in both groups: EVLA (42, 27.7%) versus EVGA (32, 23.8%) (Table 4).

EVLA: endovenous laser ablation, EVGA: endovenous glue ablation, GSV: great saphenous vein, DVT: deep venous thorombosis, PE: pulmoner embolia, a Residual side branch treatment after three months

During the 5-year period, 25 patients in both groups could not be reached for follow-up (Table 5). In the first and third month measurements, total occlusion was detected in both groups. At 6 months, complete occlusion was observed in 148 (98.7%) patients, and partial recanalization was observed in 2 (1.3%) patients in the EVLA group. In the EVGA group, this was 129

(97.7%) to 3 (2.3%). At 12 months, in the EVLA group, occlusion was found in 143 (97.9%) patients, partial recanalization was found in 2 (1.3%) patients, and recanalization was found in 1 (0.8%) patient. In the EVGA group, there were 126 cases (98.4%) without recanalization and 2 cases (1.6%) with recanalization. At 24 and 60 months, the occlusion, partial recanalization, and recanalization rates in the EVLA group were 135 (97.2%), 2 (1.4%), 2 (1.4%), 121 (95.2%), 5 (3.9%), 1 (0.9%), and 115 (95.8%), 5 (4.2%), 0 (0%), 101 (93.5%), 7 (6.5%) in the EVGA group, respectively. Occlusion rates were similar at all times. However, recanalization greater than 5 cm was not observed in the EVGA group, although it did not reach statistical significance (Table 5).

In both groups, the VCSS and CIVIQ-20 evaluations showed a statistically significant improvement in the first month followup compared to the pre-procedure. In the subsequent follow-up evaluation, well-being remained consistent, and no significant difference was detected (p<0.001) (Table 6).

VFT (16.4sec \pm 4.7 to 27.6sec \pm 1.2, p<0.001) and TH (from 2.9sec \pm 0.2 to 2.3sec \pm 03, p<0.001) venous hemodynamic measurements showed statistically significant improvement in both groups compared to the first month in the EVLA group. This improvement in well-being continued at the end of 5 years. Similarly, it was observed in the EVGA group that the VRT increased from 20.3 sec \pm 5.0 to 31.1 sec \pm 4.0 (p<0.001), and the TH decreased from 2.8 $sec \pm 0.3$ to 2.4 $sec \pm 0.2$ (p<0.001). The measurement values at the follow-up times are shown in Table 6.

VCSS: Venous Clinical Severity Score, CIVIQ20: Chronic Venous Insufficiency Questionnaire, VRT: venous refilling time, TH: venous half-value time, *P value: comparison of VCSS, CIVIQ20, VRT and TH measurements at pre-intervention and 60 months

DISCUSSION

In this study, we retrospectively analyzed the 5-year results of 152 patients who underwent EVLA and 133 patients who underwent EVGA. Unlike other studies, we also evaluated the hemodynamic effectiveness of the conducted procedures.

Both groups had similar demographics and baseline characteristics.

The EVLA and EVGA procedures were performed as described

by Bozkurt et al. [16]. All procedures were completed successfully with a 100% success rate.

Our plan for EVGA was to attach the adhesive-filled delivery catheter to the injection gun, then insert the tip 1.5 cm distal to the saphenofemoral junction, and deliver the cyanoacrylate under ultrasound guidance. However, in the first case, we were unable to inject the glue after placing the catheter in the correct position. We discovered that the cause of this issue was the presence of blood inside the catheter, which caused the glue to harden as the catheter was being inserted. For this reason, we used a second catheter. This time, we filled the catheter with saline and placed it correctly. We proceeded with the application without encountering any issues in the following cases.

The main difference between the procedures was the use of EVLA tumescent anesthesia, which resulted in a longer procedure duration (28.2 seconds \pm 8.5 versus 7 seconds \pm 0.7, p<0.001) and a higher level of pain experienced during the procedure $(10.1\pm2.2$ versus 1.5±0.8, p<0.001). Şahin et al., in their article published in 2022, similarly stated that the procedure time was longer in the EVLA group [17]. In the article published by Çalık et al. in 2019, similarly, it was stated that the EVLA group had less pain during the procedure [18].

Tumescent anesthesia volume was 252 mL. In the EVLA group, as well as in thin patients and patients with superficial GSV, a larger amount of tumescent anesthesia was administered, specifically targeting the skin and the upper part of the GSV. However, we did not measure and evaluate patients with GSV close to the skin. Wallece et al. described tumescent anesthesia to avoid thermal injury. Eggen et al. stated that the use of tumescent anesthesia during endovenous thermal ablation in 62 patients was a simple, safe, inexpensive, and effective way to reduce perioperative and early postoperative pain [19,20].

There was a statistically significant improvement in VCSS $(p<0.001)$ and CIVIQ-20 scores $(p<0.001)$. These improvements started in the first month for both groups and continued until the end of the five-year period. There was no statistically significant superiority between the EVLA and EVGA groups in this area. In the Varico 2 study, Lawson et al. found that EVLA with a 1470 nm radial fiber yielded superior outcomes in terms of early postoperative venous clinical severity scores, as well as pain and physical quality of life scores [21].

There were no major complications, such as DVT or PE, observed in post-operative follow-ups. Spinedi et al. reported that DVT formation was prevented in 113 patients with EVLA by using a technique in which the laser tip was placed 1.5 cm behind the SFJ [22].

Temporary ecchymosis ($n=14$, 9.1% versus $n=10$, 7.5%) and skin pigmentation ($n=3$, 2.3% versus $n=2$, 1.3%) were observed in both groups during the early period. These complications are not related to ablation but may be associated with the placement of a central intravenous catheter [23]. While induration (22- 14.4% versus 10-7.5%, p<0.001) and paresthesia (9-5.9% versus 0, $p<0.001$) were more common in the EVLA group during the early period, stiffness was higher in the ablated GSV tract in the EVLA group. Induration and paresthesia may be caused by high temperatures or inadequate tumescent anesthesia, as mentioned in previous publications [24, 25]. The hardness in EVGA may be due to improper pressure application during the process, causing it to solidify as a result of its own volume. However, these conditions improved after three months. We believe that these minor complications may be attributed to the patients' thinness, superficial great saphenous vein (GSV), and large diameters of the GSV. After the third month, miniphlebectomy or foam treatments were performed as necessary. In the EVLA group, 42 (27.7%) patients underwent these procedures, while in the EVGA group, 32 (23.8%) patients received them.

Venous hypertension, which is associated with the development of cardiovascular venous disease (CVD), is a condition where the pressure in the veins of the lower leg and foot does not decrease normally when the calf muscles contract. This is most often caused by insufficient valves in the veins. Venous dilatation is caused by hydrostatic pressure, which is a physical factor. The volume overload caused by superficial venous reflux increases the hydrostatic pressure force [26]. DPPG is the only non-invasive measurement tool that helps us understand CVD from this perspective [27]. VRT is the primary parameter of the D-PPG curve. When you stand or sit still, blood accumulates in your calves. Leg elevation and calf pumping help improve blood circulation and remove stagnant blood. When you lie down or stop pumping, the pressure gradient reverses, but the valves in your veins close to prevent blood from flowing back down your legs. The valves reopen when your veins have been refilled. Normal plethysmographic VRT measured at the end of ten-foot flexion and dorsiflexion is greater than 25 seconds in healthy individuals. If you have vein incompetence, the valves in your veins may not close properly, allowing blood to flow back down your legs. This will shorten the VRT time [28]. The "TH" refers to the time when half of the pumping capacity is reached during the refilling phase (also known as the resting phase), and when half of the amplitude has been reached again. Therefore, the value "TH" does not indicate half of "VRT".

The uncertainty in defining occlusion and recanalization in ablated GSV, which is evaluated using Doppler USG and considered a criterion for success, actually makes all the studies incomplete in a sense [4, 16]. We believe that hemodynamic measurements should be given more prominence in this context. In our study, we observed a statistically significant improvement in venous hemodynamic parameters in both groups, regardless of the occlusion rates of the treated GSV. This may indicate that the volume of backflow from the treated GSV is reduced, even in cases of recanalization.

While there were close to 100% closure rates in both groups during the first 6 months, the rates decreased slightly to 95.2% in EVLA and 93.5% in EVGA by the end of the fifth year. These rates are similar to those found in other studies [29]. In a single study, Balaz et al. reported that the occlusion rates were 65% after 1 year in patients who underwent EVGA [4]. The results of this study may be attributed to the learning curve, which could be due to inadequate pressure, a low volume of cyanoacrylate, or the speed at which the catheter is retracted. This is supported by the high rate of procedural failure, which is currently at 87%.

In our study, we found that the EVGA method is as reliable and effective as EVLA, and it is more comfortable for both the patient and the practitioner. Although the occlusion rates at the end of five years were better in the EVLA group, no statistical significance was found.

Both methods provide a significant improvement in patient complaints by preventing high venous volume, which can lead to venous hypertension. We have also demonstrated this with D-PPG.

The fact that both methods show similar success in terms of hemodynamic and subjective improvement, without one method being superior to the other, highlights the relatively less invasive EVGA as the preferred option.

Apart from that, EVLA requires more expensive technical materials and equipment. It also involves adjusting the joule given according to the vessel diameter during the procedure. Additionally, the need for additional technical staff may be another reason why EVGA is preferred by practitioners.

As a result, we believe that EVGA may be preferred by patients and physicians because it does not require tumescent anesthesia, reduces pain, and shortens the procedure time.

There are limitations to this study. Most importantly, the study population was from a single center and was assessed retrospectively by a single surgeon, which could introduce potential bias in the reporting. Lack of standardization in assessing occlusion rate may impact the results of studies. For this reason, there is a need for new prospective, large-scale studies to determine standardization. In addition, more randomized and large-scale studies are needed to evaluate whether EVLA or EVGA is superior in thin patients with superficial GSV and in patients with a GSV greater than 9 mm.

CONCLUSION

EVLA and EVGA are effective and safe methods for treating CVD. Both have their own advantages and disadvantages. EVGA may be more preferred by patients because it does not require tumescent anesthesia, causes less pain, and has a shorter procedure time. However, any method that reduces the volume of blood in the distal venous bed and consequently lowers venous blood pressure appears to be beneficial for patients with CVD.

Ethics Committee Approval: The study protocol was approved by the Uludag University Clinical Research Ethics Committee (Desicion Number: 2023-17/6)

Patient Consent for Publication: Individual informed consent was waived due to retrospective design.

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

Author Contributions: All authors contributed equally to the article.

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