ORIGINAL ARTICLE

The level of occlusion of small saphenous vein after endovenous laser ablation

Anel Okić[1], Hasib Mujić[2], Amel Hadžimehmedagić[3], Nermina Babić[4], Alma Krvavac Hafizović[3], Azra Kajmaković Kožo[1]

[1]Department of Breast Unit, Cantonal Hospital, Zenica, [2]Chicago Vein Institute, Sarajevo, [3] Department of Vascular Surgery, Clinical Centre of University Sarajevo, [4]School of Medicine, Sarajevo; Bosnia and Herzegovina

ABSTRACT

Aim To determine the success of endovenous laser ablation (EVLA) treatment and long-term occlusion of small saphenous vein (SSV), as well as factors and conditions that influence the effectiveness of EVLA treatment.

Methods A total of 250 patients treated with EVLA method over a period of seven years were followed one year after treatment. The main factors monitored and recorded during EVLA treatment were laser power (W), amount of delivered energy (J), duration of treatment (sec), veins length (cm), diameter (mm) and reflux (sec).

Results Within the first six months, the recanalization or insufficiently occluded SSV was noticed in ten, and after one year in one patient. The overall assessment of occlusion and satisfactory findings after one year of SSV was 95.6%.

Conclusion It is important to choose adequate power and the amount of delivered energy. The physician's assessment and selection of an adequate patient greatly improves the outcome of the treatment. It is important to treat larger branches and double SSV between two fascias. Successful and effective EVLA treatment greatly reduces the possibility of recanalization of the treated vein.

Key words: laser energy, laser power, occlusion, varicose vein

Corresponding author:
Anel Okić
Department of Breast Unit,
Cantonal Hospital Zenica
Crkvice 67, 72 000 Zenica,
Bosnia and Herzegovina
Phone: +387 32 405 133;
Fax: +387 32 405 534;
E-mail: anel_okic@yahoo.com
ORCID ID: https://orcid.org/0009-0003-7587-5856

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INTRODUCTION

Small saphenous vein (SSV) is a part of the superficial venous system of the leg that serves to evacuate venous blood mainly from the back and lateral segment of the leg towards the saphenopopliteal junction. It is believed that about 15% of varicose veins on the lower leg are caused by insufficient SSV (1). The SSV extends from the lateral malleolus to the back of the knee where it empties into the *v. poplitea*. It is mostly followed by the sural nerve (1).

SSV surgery is considered more challenging than great saphenous vein surgery and is associated with a higher rate of recurrence and postoperative complications (2). The treatment of the SSV must be carried out very carefully because the final lower part of the SSV is variable, and it is located in close proximity to the nerves (2).

However, during the 1990s and with the development primarily of endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) methods, significantly better results were achieved in the treatment of the SSV. These procedures are associated with several advantages, including a minimally invasive nature, immediate discharge and mobility, faster recovery, and less per procedural morbidity. It appears to have high anatomic success rates compared to traditional surgical treatment (3,4).

The EVLA of insufficient SSV is a minimally invasive, safe and effective treatment method with a high success rate (5). In the current practice of performing EVLA, a number of factors have been noted that have an impact on the long-term occlusion of targeted veins after EVLA treatment (5,6).

Many factors that have an impact on EVLA results influence long-term SSV occlusion as a treatment goal. These factors are usually divided into two groups: factors influenced or not of doctors. Some of the factors that have an impact on EVLA results, which depend on a doctor are: laser power, amount of delivered energy per centimetre treated with the SSV, the speed of pulling out the fibre from the SSV (it was standardized in our study at 1 mm/second) (7). Factors beyond doctor’s control are the age of patients, length and diameter of treated SSV, the number of SSV ramifications and the level of SSV insufficiency, anatomical variations of the SSV (double SSV, coming out of the fascia, communication with posterior perforators, perforators that directly “flow” into the SSV, etc.) (8).

The power of the laser and the amount of energy used during the EVLA treatment is still not clearly defined, so doctors rely on their own experience and judgment (9). An “ideal” amount of energy that will not cause complications and will be sufficient for complete, long-term occlusion of the lumen of the SSV is still under research (9). There is a number of studies that have been done for the great saphenous vein (10,11) but no details on the long-term occlusion of the SSV. Research of the SSV occlusion and impact of various parameters on the final result is needed by clinicians in order to have the best possible effect after the treatment, and the obtained results will be able to be used with other comparative research.

The aim of this study was to determine the success of endovenous laser ablation (EVLA) treatment and long-term occlusion of the small saphenous vein (SSV), as well as factors and conditions that influence the effectiveness of EVLA treatment, the laser power, the duration of the treatment and the amount of delivered energy.

PATIENTS AND METHODS

Patients and study design materials

In this retrospective study the success of long-term occlusion of the SSV in patients who were treated with EVLA with a 1470 nm laser was investigated. A total of 250 patients who were treated with EVLA during the period of seven years (January 2015 to May 2021) were randomly selected (one patient every week or every second week), and followed-up for six months and one year after the treatment.

Inclusion criteria were the patients who underwent the EVLA method, followed-up examination after six months and one year, older than 18 and younger than 75 years, and patients with the consent that the data could be used for research purposes, patients.

Exclusion criteria were the cases when the SSV were not occluded immediately on control after 72 hours, SSV in children younger than 18 years, very short SSV (shorter than 2 cm or with signs of thrombophlebitis).

All patients signed a written consent for inclusion in the investigation.

Methods

The research included the patients with insufficient SSV who were treated with EVLA. The factors monitored and recorded during EVLA treatment were: laser power (W), amount of delivered energy (J), duration of treatment (min:sec), length of treated vein (cm), as well as vein diameter (mm) and vein reflux (sec).

The examined patients and the parameters were measured according to other similar studies (12, 13,14).

All patients were processed clinically and diagnostically. Ultrasound examination of the venous system of the lower extremities was performed with an ultrasound device (Biosound Esaote MyLab 25 Xvision, Esaote SpA, Genoa-Florence Italy) (probe 5-10Hz). The assessment of the sufficiency of the SSV venous valves was performed in the standing position of the patient with provocative manual manoeuvres and measurement of retrograde venous flow. Retrograde flow of venous blood longer than 500 ms for SSV defined as its insufficiency (15).

Clinical, etiological, anatomical and pathophysiological (CEAP) classification (9) was given for each patient, and EVLA of insufficient SSV was performed. EVLA was performed under ultrasound control under local tumescent anaesthesia using the TermaLite 1470 diode laser TotalVein (Houston-Texas, USA,) (12W, 1470 nm). Under ultrasound control, a needle with a diameter of 18G (for SSV) was percutaneously cannulated, after which a S01-6100-BF-0 fibre with a diameter of 600 µm for single use was inserted through the needle, a maximum of 1-2 cm from the mouth of the SSV into the popliteal vein. The position of the tip of the laser thread was confirmed in addition to ultrasound and visualization of red light under the skin. After the EVLA treatment, a compression stocking with a density of 70-120 den was applied, with a pressure of 25-35 mmHg on the skin and an elastic bandage for 72 hours, after which an ultrasound control of the treated veins was performed in order to establish an occlusion of the treated veins. The compression sock was worn during the day for the next 30 days, and according to our experience, for the most ideal results, it was recommended that the elastic sock be worn for the next 3 months. After the treatment, the patients were prescribed antibiotics for 3 days and NSAIDs (non-steroid anti-inflammatory drugs - ibuprofen) as needed by the patient within 24-48 hours after the treatment. Ultrasound control of treated veins was performed after 6 and 12 months after treatment.

Statistical analysis

Pearson's and Spearman's correlation, Anova and Mann Whitney Test were used. Anova, or Analysis of Variance, was used to compare means among our groups. The Mann-Whitney test was used to determine a difference between two independent groups. Spearman's correlation (Rho) was calculated by ranking the values of both variables and then computing the Pearson correlation coefficient for the ranked values. The $p<0.01$ and $p<0.05$ (2-tailed test) were used for statistical significance.

RESULTS

Among 250 patients, 75 (30%) were males and 175 (70%) females. The overall average age was similar in both genders, 35 years.

The average diameter of the vein was 4.2 mm (25^{th} and 75^{th} percentile range 3.6-5.15 mm). The minimum measured diameter was 2.3 mm, and the maximum was 8.4 mm. The average reflex was 705 (ms) (25^{th} and 75^{th} percentile range 570.25-1047.0). The average power of the laser used in the treatment was 6 W, the minimum was 4.6 W, and the maximum was 7.5 W. The average energy was 1251.0 J (25^{th} and 75^{th} percentile range 919.86-1555 J). The average treatment time was 202.5 s (25^{th} and 75^{th} percentile range 149.75-257.25 s). The average length of the vein was 25 cm (range 20-30 cm). The minimum length of the treated vein was 5 cm, and the maximum was 61 cm (Table 1).

Table 1. Average values of the researched variables of 250 patients with long-term occlusion of small saphenous vein (SSV) treated with endovenous laser ablation (EVLA)

Variable	Min./Max.	Percentile		
		25^{th}	50^{th} (Median)	75^{th}
Vein diameter (mm)	2.30/8.40	3.60	4.20	5.15
Reflux	74.00/2916.00	570.25	705.00	1047.00
Power (W)	4.60/7.50	6.00	6.00	6.00
Energy (J)	181.70/3581.20	919.85	1251.00	1555.00
Time(s)	30.00/551.00	149.75	202.50	257.25
Vein length (cm)	5.00/61.00	20.00	25.00	30.00

Table 2. Correlations between measured variables of 250 patients with long-term occlusion of small saphenous vein (SSV) treated with endovenous laser ablation (EVLA)

Variable		Power (W)	Energy (J)	Diameter (mm)	Reflux (s)	Treatment duration (s)	Length (cm)	Age (years)	Gender (F/M)
Power	Rho		.228	.146	.131	.060	.037	.026	-.028
	p		.0001	.021	.039	.345	.556	.686	.655
	N		250	249	250	250	250	250	250
Energy	Rho	.228		.065	.179	.945	.863	-.083	-.212
	p	.000	.	.307	.005	.0001	.0001	.191	.001
	N	250		249	250	250	250	250	250
Diameter	Rho	.146	.065		.215	.065	-.018	.058	-.093
	p	.021	.307	.	.001	.308	.778	.359	.143
	N	249	249		249	249	249	249	249
Time	Rho	.060	.945	.065	.176		.875	-.095	-.219
	p	.345	.0001	.308	.005	.	.0001	.136	.0001
	N	250	250	249	250		250	250	250
Length	Rho	.037	.863	-.018	.182	.875	1.000	-.057	-.178
	p	.556	.0001	.778	.004	.0001	.	.366	.005
	N	250	250	249	250	250	250	250	250

N, number of patients

Laser power was positively correlated with energy (Rho=0.228; p=0.0001), with vein diameter (Rho=0.146; p=0.021), and with reflux (Rho=0.131; p=0.039). Laser power was not correlated with other measured variables, treatment time, vein length, age and gender of the patients (>0.05).

Energy was correlated rho=0.179 with reflux (Rho=0.131; p=0.005), with treatment time (Rho=0.945; p=0.005), with vein length (Rho=0.863; p=0.005), and with gender (Rho=-0.212; p=0.01). Energy was not correlated with other measurement variables (p>0.05).

Vein diameter was correlated with reflux (Rho=0.215; p=0.001).

The diameter of the vein was not correlated with other measured variables (p>0.05).

Reflux (ms) was correlated with length/time of treatment (Rho= 0.176; p=0.005), with vein length (Rho= 0.182; p=0.004), but it was not correlated with the age and gender of the patients (p>0.05). The age of the patients was not correlated with the measured variables (p>0.05). Gender of the patients (m/f) was correlated with energy (Rho=-0.212; p=0.001) (males received less energy), the treatment time (rho=-0.219; p=0.0001) (males were exposed to a shorter treatment time), and with vein length (Rho=-0.178; p=0.005) (males had smaller lengths of veins subjected to treatment).

Laser power showed a positive correlation with energy, vein diameter and reflux, while it did not correlate with other parameters such as duration of the treatment and vein length. The delivered energy was correlated with reflux, duration of the treatment, vein length and with the subject's gender. It was also found that male subjects received less energy, the treatment lasted shorter and the length of the treated vein was shorter (Table 2).

A strong, linear relationship between delivered energy and vein length was found (Rho=945; p=0.005) (Figure 1).

After 6 months, 10 (out of 250; 4%) the patients underwent again the EVLA treatment (reEVLA).

After 12 months, one (0.4%) patient underwent reEVLA treatment; this patient was excluded from the other 10 who underwent the reEVLA treatment after 6 months, before the first follow up (one year after treatment).

The average power used after 6 months was 6 W (range 6-6.5 W), with the energy of 209.6 J,

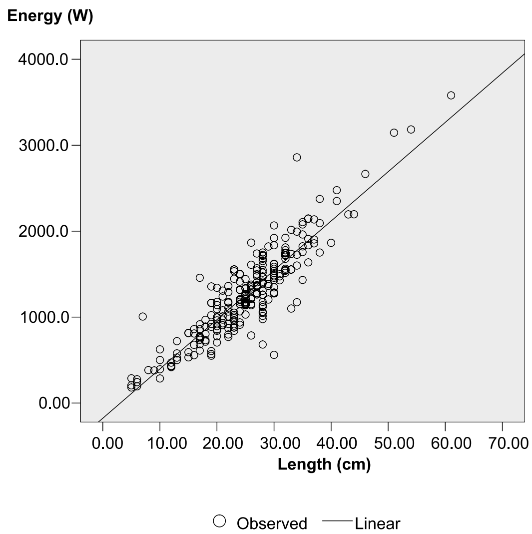

Figure 1. Relationship between used energy and vein length (Rho=945; p=0.005)

(range 154- 371.2 J). The minimum energy was 101.10 J, and the maximum was 479.4 J.

The duration of the treatment in 10 patients after 6 months was 34.5 s on average (range 25.5 s to 60 s). The minimum duration of the treatment was 16 s, and the maximum was 73 s.

The average length of the vein was 6 cm (range 5.5-10 cm). The minimum length for the treatment was 2 cm, and the maximum length was 11 cm.

In total 10 (4%) patients, after 6 months, underwent the reEVLA treatment; 240 (96%) patients did not require the second treatment. After 12 months, one patient underwent the reEVLA treatment with a power of 6W, energy of 1050.2 J, a time of 175 s, on a vein length of 23 cm. The same patient had no reEVLA treatment after 6 months (Table 3).

Table 3. Average values of strength, energy, time and vein length in 10 patients with long-term occlusion of small saphenous vein (SSV) treated with endovenous laser ablation (EVLA) after 6-month follow-up

Variable	Min./Max.	Percentile		
		25th	50th (Median)	75th
Power (W)	5.00/6.50	6.0	6.00	6.125
Energy (J)	101.10/479.40	154.9	209.6	371.2
Time (s)	16.00/73.00	25.25	34.50	60.00
Vein length (cm)	2.00/11.00	5.50	6.00	10.00

DISCUSSION

According to the results of Boersma et al. study (3), 2950 SSV were treated with EVLA with occlusion success rate of 97.1% suggesting that EVLA should have an advantage over surgery and sclerotherapy in the treatment of SSV insufficiency. Our results match the data from Boresma study, confirming a dominance of the EVLA for the SSV occlusion.

In a study conducted on 204 patients (229 SSV) complete occlusion with no flow after 2 months of follow-up was detected in 98.7%; recanalization was found in one patient after 12 months and in two patients after 24 months (14). Our research matches the results of this study. The results of our study proved the efficiency of the EVLA procedure, as well as the percentage of recanalization; our research showed that the percentage of insufficient SSV occlusion within 6 months existed in 4% patients, and after a year in 0.4% (one patient), as well as the percentage of satisfactory occlusions with EVLA treatment of SSV was 95.6%.

According to Aursina et. al. study (15) for 1475 thermal ablations in 401 patients with insufficient SSV and defined a recurrence as >500 ms for the SSV, low overall recanalization rates after thermal ablation of the GSV and SSV was found. We confirmed the same with our results. Aurisna results showed a higher rate of recanalization within female patients (15). Our research confirmed a correlation between laser energy and patient's gender (female patients received more energy). Our recommendation is to increase the amount of energy when we treat female patients.

In Kubat et al. study the result showed that EVLA is a dominant procedure for the treatment of great saphenous vein GSV with the diameter of 10 mm and less comparing to high ligation and open surgery, and radiofrequency ablation RFA (16).

Investigating factors of EVLA treatments it was found that power and linear endovenous energy density (LEED) are separate but important determinants of short-term EVLA success; while the ideal values for power and LEED differ depending on the clinical scenario, the findings suggest that using higher power outputs and higher LEED values (≥90% probability of success achieved with power >10.34 W or LEED >26.56 J/cm) can give optimal results (17,18).

In a randomized clinical trial comparing EVLA and surgical ligation with attempted SSV stripping for complete treatment of SSV insufficiency, of 106 patients who were equally randomized and successfully treated according to the protocol, 83% were successfully treated after 2 years; EVLA remained superior to surgery in 81.2% compared with 65.9% in the surgery group (19).

The Kibrik et al. study (20) of patients with chronic venous insufficiency of the SSV, the mean diameter of target veins for repeat ablation was 4.51±1.33 mm and showed premature closure of 96.7% with no correlation found between successful obliteration with re-procedure and age, gender, clinical etiological anatomical pathophysiological (CEAP) class, laterality, EVLA versus radiofrequency ablation (RFA), body mass index (BMI), or vein diameter.

In our research patients' gender was correlated with energy and treatment time, males received less energy and were exposed to a shorter treatment time. We did not find any correlation between the patients' age and other parameters. There is no specific and current data about the difference for male and female treatment. Other studies mainly do not separate patients by gender (21).

In our research there is a small number of recanalization in SSV when some of the larger branches or double SSV were treated either partially or even completely with EVLA in the space between the two fascia. No correlation was observed between the diameter and the length of reflux and SSV recanalization within one year.

The limitation of the research is small number of patients and unequal time interval of the control examination.

In conclusion, we proved the strong correlation between laser power, delivered energy and vein diameter and between delivered energy and treatment time, vein length and gender. These results confirmed the importance of parameters that we can have an impact during the treatment. We have managed to standardize the speed of pulling out the laser fibre to 1 mm per second. It is important to choose adequate power and the amount of delivered energy. We recommend the 6 W laser power for SSV occlusion and the amount of energy between 919.86 J and 1555 J to avoid recanalization.

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TRANSPARENCY DECLARATION

Conflict of interests: None to declare.

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