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Endothermal heat-induced thrombosis after endovenous laser ablation in diabetic patients with varicose disease with different energy modes

Abstract
Aim: Endothermal heat-induced thrombosis (EHIT) is defined as propagation of a thrombus from a superficial vein into a deeper vein and is generally considered clinically insignificant if the thrombus does not propagate to the deep venous system. The condition can be treated with anticoagulation therapy, although monitoring may be sufficient, especially in less severe cases. Endovascular laser ablation (EVLA) have become popular techniques for treating varicose veins. Endothermal heat induced thrombosis is a complication unique to endovenous ablation. It reflects the extension of the thrombus from the ablated saphenous vein into deep venous system. Endovenous laser ablation in patients with diabetes mellitus is not well published. To compare the endothermal heat induced thrombosis incidence rate after EVLA performed with three different energy densities. The outcomes of the 140 patients with diabetes after EVLA were analyzed.
Material and Methods: 80-100 J/cm energy was applied in the 1st group (n=60), 100-120 J/cm in the 2nd (n=40), and 120-140 J/cm in the 3rd group (n=40) patients. All patients received Enoxaparin 40mg subcutaneously, for thrombose prevention after EVLA for 7 days.
Results: There were 32 EHIT cases (22.86%) detected with duplex US investigation 7 days after EVLA. The incidence rate among groups was 31.7%, 20%, and 12.5% accordingly.
Conclusion: The analyses show that 120-140 J/cm energy density is the most safe and effective treatment mode for EVLA in patients with diabetes mellitus.

Keywords: Varicose vein, endovascular laser ablation, energy density, endothermal heat-induced thrombosis, outcomes

INTRODUCTION

Chronic venous insufficiency (CVI) and varicose veins are worldwide spread pathologies. Endovenous laser ablation is a minimally invasive procedure mostly used for the treatment of varicose disease. The 80–100 J/cm energy power was suggested as an optimal mode for the Endovascular laser ablation (EVLA) in the treatment of superficial veins (1,2). The impact suggested energy density on vein walls in patients with diabetes mellitus is an interesting subject for investigation. The vein walls in patients with chronic venous insufficiency, who suffered from diabetes mellitus, over the years became sclerotic (3,4).

Endothermal heat induced thrombosis is one of the postoperative phenomena after endothermal ablation of superficial veins related to retention thrombus in the lumen of the adjacent deep vein. Definition, classification systems, pathophysiology, risk factors, treatment, and prevention of Endothermal heat-induced thrombosis (EHIT) have already been well published (5-7). But there are still not-sufficient data about the impact of the different energy density of EVLA on the development and severity of EHIT.

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Aim

To study the impact of different energy density modes of EVLA in patients with diabetes mellitus.

MATERIAL AND METHODS

140 patients (98 women and 42 men) suffering from varicose veins of the lower limbs and type 2 diabetes as a comorbid disease were enrolled for the prospective randomized investigation. EVLA procedure was performed for the treatment of patients. Procedures were led between 2017–2020 years at the Istanbul NS Clinic in Baku and in “Yeni Ganca” medical center in Ganja, Azerbaijan. Ethics Committee of State Advanced Training Institute for Doctors named after A. Aliyev has approved our study on October 16th, 2019, protocol 5. The average age of the patients was 57.1±0.62, ranging from 41 to 74 years, and diabetes anamnesis was 13.8±0.33 years.

Patients were divided into control and basic groups depending on energy density. According to the international guidelines the suggested energy density (80–100 J/cm) was performed in the control group (n=60). The other 80 patients were selected as the basic group. For the effective obliteration of the varicose veins, the energy density was steadily increased. With the stratification of the energy density, the basic group patients were also divided into two subgroups: subgroup A –energy density 100–120 J/cm and subgroup B –energy density 120–140 J/cm.

The patient’s enrollment into the groups for performing different energy modes was done randomly. Patients admitted in the period of 01.12.2017-31.01.2019 were enrolled to the control group. Patients admitted in the period of 01.05.2019-31.05.2019 were enrolled to the subgroup A, and patients admitted from November 2019 to March 2020 were enrolled to the subgroup B in the basic group.

According to study inclusion and exclusion criteria EVLA procedure is assigned for all patients. Venous hemodynamics before and after EVLA were examined by the duplex ultrasound method using the Siemens Acuson P300 device (Erlangen, Germany).

Laboratory tests showed average blood glucose concentration of 176.3±6.16 mg/dl. and HbA1 concentration of 8.4±0.13%. CEAP (Clinical Etiological Anatomical Pathophysiological) classification was used for the evaluation of clinical performance of venous insufficiency. Figure 1 shows the CEAP classification for the evaluation of the chronic venous insufficiency of right limb and Figure 2 shows the CEAP classification for the left limb.

Venous Clinical Severity Score (VCSS) was calculated for identification of the severity of venous insufficiency of lower limbs. In Table 1 the VCSS parameters values before EVLA procedure for all patients were shown.

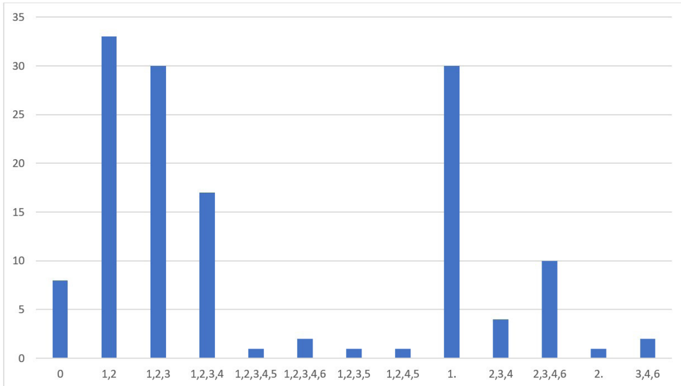

Figure 1. CEAP classification for the right limb

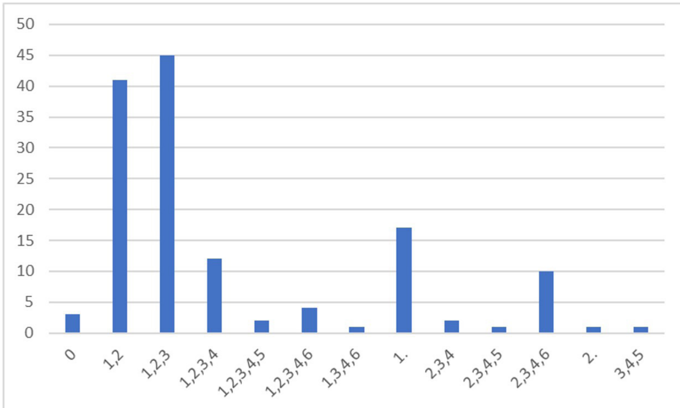

Figure 2. CEAP classification for the left limb

Table 1. Preoperative VCSS evaluation for both sides

	Pain	Varicose veins	Oedema	Hyper pigm.	Inflam mation	Induration	Ulcer num.	Ulcer durat.	Ulcer size	Comp. stock.
Right										
M	1.03	2.77	1.17	0.66	0.30	0.56	0.20	0.34	0.23	0.55
m	0.08	0.04	0.097	0.097	0.074	0.096	0.05	0.085	0.06	0.086
min	0	2	0	0	0	0	0	0	0	0
max	3	3	3	3	3	3	2	3	3	3
Left										
M	1.06	2.70	1.07	0.53	0.26	0.41	0.17	0.27	0.21	0.65
m	0.07	0.049	0.086	0.083	0.06	0.073	0.05	0.07	0.06	0.085
min	0	0	0	0	0	0	0	0	0	0
max	3	3	3	3	3	3	3	3	3	3

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EVLA was performed with a "Biolitec ELVeS Radial 2 Ring Fiber™" (Germany) diode laser device and a catheter with a wavelength of 1470 nm (7,8). All EVLA procedures were performed under Tumescent local anesthesia. As a single procedure the mini-phlebectomy was performed on patients according to the indications. For the prevention of thrombosis Enoxaparin 40 mg was administrated subcutaneously, once a day for 7 days. Class II elastic compression stockings were recommended for all patients. Patients were examined 1 week, 1 month, 6 months, and 1 year after EVLA. The primary criterion was the EHIT rate and the secondary varicose reflux recurrence rate.

EHIT was graded according to the AVF-EHIT Classification (9). The below given 4 Classes of EHIT were defined in this classification:

Class I -thrombus without propagation into the deep vein.

a) peripheral to the superficial epigastric vein.

b) central to the superficial epigastric vein and up to the deep vein junction.

Class II thrombus propagation into the deep vein, <50 % of the deep vein lumen.

Class III thrombus propagation into the deep vein, >50 % of the deep vein lumen.

Class IV thrombus propagation results in occlusive deep vein thrombosis and is contiguous with the treated vein.

Statistical Procedure

The data collected during and at the end of examinations has been systemized in Excel tables. The Mean and standard error (M±m), as well as the minimum and maximum values, have been calculated.

The power analysis has been conducted to determine the sample size. The sample size is sufficient for the statistical procedure and for the achieving endpoints.

Parametric and non-parametric methods have been used to compare the results between the basic and control groups, as well as between the two subgroups of the main group. Differences between indicators have been considered significant when $P<0.05$. Dispersion analysis has been used by determining the F-critical value in comparison of several groups for numerical signs, and a two-sided t-coefficient has been used for comparing 2 groups by Student's method. Statistical processing has been performed on a personal computer using the IBM SPSS-21 statistical program.

RESULTS

1 week after EVLA in the control group total 19 cases (31.7%) were detected. Among these patients, in 4 cases (6.7%) the I class, and in 15 cases (25%) II class were defined (Table 2). The VCSS score parameters in the control group were also not sufficient. Pain intensity, varicose veins, edema, and inflammation showed a significant improvement compared to the preoperative results ($p<0.01$). Despite 1 week after surgery, there was no significant difference in VCSS parameters such as hyperpigmentation, subcutaneous induration, ulcer number, ulcer duration, and ulcer diameter ($p>0.05$).

In subgroup A, endothermal induced thrombosis was detected in 8 patients (20%). The EHIT was graded as Class I and patients did not have any serious complaints. After a physical examination and VCSS evaluation, these patients were invited for future follow-up. There was a significant positive effect on parameters such as pain, number of varicose veins, and edema 1 week after EVLA in this subgroup. Better results were obtained regarding improving most VCSS parameters.

Table 2. EHIT incidence rates in patients 1 week after EVLA

	I Class		II Class		Patients number	EHIT cases	%
Control	4	6.7%	15	25%	60	19	31.7%
Subgroup A	8	13.3%	0	0	40	8	20%
Subgroup B	4	6.7%	1	1.70%	40	5	12.5%
Total count	16	11.43%	16	11.43%	140	32	22.86%

1 week after EVLA, in subgroup B, a significant decrease in the pain intensity in the right lower limb was detected. 4 patients (6.7%) with Class 1 and 1 patient with Class 2 EHIT were observed according to US examination. The total EHIT rate in subgroup B was 12.5%. The complication rate in subgroup B, regarding the post-operative EHIT was significantly lower than in the control group and in subgroup A also ($p<0.05$). Table 2 shows the EHIT incidence rate in patients 1 week after EVLA.

In subgroup B, VCSS scores were better compared to both control group and subgroup A. Earlier reduction of the intensity of pain and edema, and disappearance of chronic venous symptoms ensured early rehabilitation of patients. Rapid reduction in ulcer sizes and the shorter healing time proved the effectiveness of this energy power.

8 out of 60 diabetic patients in the control group (13.3%) had a recurrence of varicose veins at different times after EVLA. Despite the use of EVLA with higher energy than the standard energy given in the control group, the recurrences rate was still high (12.5%).

The increasing energy up to 120–140 J/cm shows their powerful impact. 6 months after performing EVLA with 120-140 J/cm

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energy density only in 1 patient (2.5%) recurrence of varicose veins was observed. After repeated EVLA problem was solved.

DISCUSSION

The literature available on EHIT is largely based on retrospective studies, small case series, and case reports. Therefore, the quality of evidence on prevention and risk factors associated with EHIT is very low. The design of these studies reflects the difficulties of gathering a substantial amount of data to justify a prospective, randomized study. The main reason for it is the very low incidence of EHIT in the vast cohort of patients treated with endovenous ablation despite some reported high incidence of thrombotic complications in the literature. The incidence of DVT after EVLA has been described to be as high as 16% (10). Similarly, the incidence of EHIT has been reported to be as high as 12% (11). These are relatively small cohorts analyzed retrospectively. A randomized double-blind controlled trial comparing radiofrequency and laser vein ablation reported no post-procedure thrombotic complications such as DVT (12). Aside from some outlier series, the incidence of EHIT has been demonstrated to be often lower than 3% (13,14). In the updated and expanded systematic review using PubMed and EMBASE, 4584 publications from 2000 to 2020 were screened. After applying the inclusion and exclusion criteria, 72 studies were included. The incidence of postoperative EHIT was 6.6% (15).

Previously, ablation was performed in 2.0-2.5 cm distal sections from the relevant deep system nodes. Apart from recanalization, common sources of recurrent reflux after EVLA are residual or newly developed reflux in the SFJ branches and accessory vessels, especially in the AASV (16-20). To prevent this, a method called laser crossectomy has been proposed. In this procedure, the fiber tip is positioned precisely at the SFJ before starting the ablation. A retrospective study reported that laser crossectomy using radial fiber is feasible and safe (21). We always see more EHIT I and II during surgery than when we do laser crossectomy. Because, EHIT I: To the junction of the superficial and deep venous systems and EHIT II: Extends beyond the joint with section diameter <50%.

This study has several limitations. First, the study is not multicenter and conducted at a single institution with single center data. Second, all patients were prescribed prophylactic anticoagulants after surgery. This may affect the incidence of EHIT. Moreover, those with other comorbidities were not included in our study.

CONCLUSION

In the literature, the efficiency of EVLA varies between 92–100% (22). The energy output interval from 80 to 100 J/cm has been approved as the most optimal for EVLA.

Diabetes mellitus leads to sclerosis of the vein's walls and sclerosed veins are not amenable to treatment with standard energy density in EVLA. With the suggested energy the outcomes of the treatment were not sufficient. EVLA performed with an energy of 120–140 J/cm has a more effective effect on the walls of the veins in diabetic patients compared to lower energy. The EHIT rate and varicose recurrences after EVLA in subgroup B were significantly lower than in other patients.

Conflict of Interests: The authors declare that there are no conflict of interests.

Financial Disclosure: The authors declare that there is no financial support.

Ethics Committee Approval: Ethics Committee of State Advanced Training Institute for Doctors named after A. Aliyev has approved our study on October 16th, 2019, protocol 5.

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