THE EFFECTIVENESS OF 120-140 J/CM ENERGY DENSITY FOR THE ENDOVENOUS LASER ABLATION IN PATIENTS WITH DIABETES MELLITUS

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The aim of this study is to analyze the impact of the 120-140 J/cm energy for EVLA in patients with diabetes. Material and methods. The outcomes of 40 patients with varicose disease and diabetes mellitus as a comorbid condition were analyzed. Forty patients with varicose disease and diabetes mellitus were enrolled in the investigation. There were 27 women (67.5%) and 13 men (32.5%). The average age of the patients was 59.5±1.18 years, ranging from 44 to 74 years. The blood glucose level was 184.5±11.6 mmol/l, and the concentration of glycylhemoglobin was equal to 8.5±0.25%. The average duration of the diabetes history was 10.6±0.91 years. Biolitec ELVeS Radial 2 Ring Fiber diode device and laser with 1470 nm wavelength and 120 – 140 J/cm energy were used for EVLA. VCSS results and recurrence rates were subjected to analysis in 1 week, 1 month, 6 months, and 1 year following the treatment. Results. The outcomes of the EVLA with high power energy for the treatment of varicose disease in patients with diabetes were not enough highlighted. The total VCSS score was for the right lower extremity: 4.75±0.725 - 1 week after EVLA: 1.93±0.547 - 1 month later; 0.79±0.306 - 6 months after; 0.36±0.151 - 1 year after; respectively for the left lower limb 5.37±0.806 - 1 week; 2.6±0.643 - after 1 month; 1.06±0.351 - after 6 months; 0.62±0.034 - after 1 year. 1 week after EVLA, there was an intense decrease in the pain index in the right lower limb, and after 1 month, almost 90% of the patients had no pain at all. In the 6-month and 1-year follow-ups, the pain had completely disappeared, and only 1 person reported having episodic pain. This trend is also reflected in the left leg. The intensity of pain in the left leg decreased significantly after 1 week of EVLA. During all observations, the intensity of pain was statistically significantly less than in the previous examinations (p<0.05). In the short term after EVLA the rapid reduction of the intensity of pain and oedema, and the disappearance of chronic venous insufficiency symptoms ensured earlier rehabilitation of patients. The recurrence was observed in 1 case (2.5%). Conclusion. 120-140 J/cm of energy was approved as an optimal density for the EVLA in patients with varicose and diabetes mellitus.

Key words: varicose vein, diabetes mellitus, EVLA, energy density, outcomes.

Introduction

Endovenous laser ablation (EVLA) is the minimally invasive method for the treatment of varicose disease. Laser wave frequencies ranging from 810 to 1470 nm are used to perform EVLA. The laser causes blood vessel coagulation by its heating effects resulting in the obturation [1, 2, 3]. The effectiveness of the EVLA varies from 92% to 100% based on the data of different authors. But in some cases, such as severe forms of chronic venous insufficiency, and the presence of comorbidities, the effectiveness of EVLA is reduced. The recurrence of the disease is related to the recanalization of the ablated vein and the reappearance of reflux [4, 5, 6].

In patients with diabetes mellitus, pathological changes in the endothelial layer of the blood vessels, such as sclerosis and fibrosis were observed. The reduction of the release of natural vasodilators and the intensification of the endothelial dysfunction processes caused to decrease in the possibility of vessel obliteration in the persistence of phlebosclerosis [7, 8].

Based on our self-experience we hypothesized that as a result of sclerosing of the venous vessel wall in patients with diabetes, the routinely used energy power (80 – 100 J/cm) might be insufficient to obliterate the vessel. There is a scarcity of studies devoted to the effects of diabetes on the venous system.

The purpose of this study is to analyze the impact of the 120-140 J/cm energy for EVLA to treat varicose disease in patients with diabetes.

Material and methods

Forty individuals with varicose disease and diabetes mellitus were enrolled in the study. There were 27 women (67.5%) and 13 men (32.5%); their average age was 59.5±1.18 years, ranging from 44 to 74 years. The blood glucose level was 184.5±11.6 mmol/l, and the concentration of glycylhemoglobin equalled to 8.5±0.25%. The average duration of the diabetes history was 10.6±0.91 years.

The distribution of coagulated vessels was as follows: in 25 patients (62.5%), it involved the great saphenous vein; in 4 patients (10%), the small saphenous vein was affected; in 10 patients (25%), both the small and great saphenous veins were...
involved; in 4 patients (10%), the anterior accessory saphenous vein was treated; in 3 patients (7.5%), it was a combination of the great saphenous vein and the anterior accessory subcutaneous vein; in 4 patients (10%), intravascular laser ablation was performed on both small and great saphenous veins along with anterior accessory subcutaneous veins.

Clinical manifestations of venous insufficiency were assessed using the CEAP classification. In the right lower limb, no signs of varicose disease were observed in 3 individuals (stage C0). Stage C1 was present in 9 individuals (22.5%); a combination of C1 and C2 was found in 12 individuals (30%); a combination of C1, C2, and C3 was observed in 9 individuals (22.5%); a combination of C1, C2, C3, and C4 was noted in 4 individuals (10%); and a combination of C1, C2, C3, C4, and C6 was seen in 1 individual (2.5%). In the left lower limb, the CEAP assessment of chronic venous insufficiency resulted in the following findings: Stage C0 in 1 individual (4%); Stage C1 in 4 individuals (10%); Stage C2 in 1 individual (2.5%); a combination of C1 and C2 in 7 individuals (17.5%); a combination of C1, C2, and C3 in 19 individuals (47.5%); a combination of C1, C2, C3, and C4 in 3 individuals (7.5%); a combination of C1, C2, C3, C4, and C5 in 1 individual (2.5%); and a combination of C1, C2, C3, C4, and C6 in 1 individual (2.5%).

All patients underwent to the EVLA with the 120–140 J/cm energy density. All patients were invited for follow-up examinations in 1 week, 1 month, 6 months, and 1 year after EVLA. The quality of life was evaluated according to the VCSS score. Data was gathered in the Excel sheet and the mean was calculated for all enrolled participants.

Results and discussion

The total VCSS score for the right lower extremity was as follows: 4.75±0.725 in 1 week after EVLA, 1.93±0.547 in 1 month later, 0.79±0.306 in 6 months, and 0.36±0.151 in 1 year following EVLA. Similarly, for the left lower limb, the scores were 5.37±0.806 in 1 week, 2.6±0.643 in 1 month, 1.06±0.351 in 6 months, and 0.62±0.034 in 1 year.

One week after EVLA, there was a significant reduction in pain intensity in the right lower limb, with nearly 90% of patients reporting no pain at all after 1 month. By the 6-month and 1-year follow-ups, pain had completely disappeared, and only one person reported occasional pain. This trend was also observed in the left leg. Pain intensity in the left leg significantly decreased after 1 week of EVLA. Throughout all follow-up periods, pain intensity remained statistically significantly lower compared to previous assessments (p<0.05).

The number of varicose veins decreased significantly and gradually disappeared after 1 week of EVLA. In the 1-year follow-up examinations, none of the patients had varicose veins in their right lower limbs. The intensity of the clinical manifestation of varicose veins was significantly reduced compared to the preoperative period (p<0.05). In the left lower limb, during the 1-month and 6-month follow-up observations, the clinical performance of varicose veins began to decrease rapidly, and in the 1-year follow-up observations, only 1 person had superficial vein dilatation.

Simultaneously, a reduction in oedema was also observed. Specifically, one month after EVLA, 20 individuals did not experience oedema in their left legs. Evening oedema manifested in 15 individuals. Following 6 months of follow-up, evening oedema was observed in 8 individuals, with only 1 person experiencing it after 1 year. This rapid reduction in oedema enables patients to lead a more active life and enhances their overall quality of life.

1 year after EVLA, hyperpigmentation was not detected on the left lower limb, but in 4 people, it was noted in a limited area on the right side. Any inflammation symptoms in the legs of the patients were observed in the examinations 1 month, 6 months, and 1 year after EVLA. It took some time to draw the induration process. In the observations after 1 month, the frequency of occurrence of induration in the right lower limb decreased. In the 6-month follow-up, further reduction of the induration areas was noted, and after 1 year, induration smaller than 5 cm was noted in only 2 people.

1 week after EVLA, only 1 person had 1 ulcer on the right lower extremity, but in future follow-ups, no ulcers were detected after 1 month. Also, no ulcers were found in the observations 6 months and 1 year after the operation. At the same time, in the left lower limb, after 6 months, all ulcers were completely healed, and after 1 year, there was no ulcer at all. The ulcer size reduction was faster in the immediate period after EVLA and a statistically significant result was obtained compared to the control group (p<0.05). In both lower limbs, no ulcer was detected in the observations 1 year after EVLA, and there was a statistically significant difference compared to the pre-operative period (p<0.05).

It was found that only 20% of patients used compression stockings 1 month after EVLA. This number gradually decreased and in the 1-year follow-up, only 1 person was found to be using compression stockings. Early solving of subjective complaints in patients, and the disappearance of clinical signs such as induration and ulcers reduce the need to use compression stockings.

After applying 120–140 J/cm of energy during EVLA, postoperative VCSS scores showed excellent results. Earlier reduction of the intensity of pain, the scope of oedema, and the disappearance of chronic venous symptoms ensured earlier rehabilitation of patients. In people with ulcers, the rapid reduction in ulcer size and the shorter healing time of the ulcer once again proved the effectiveness of this treatment method.
6 months following EVLA, one patient (2.5%) showed the recurrence of varicose veins. Recurrent varicocities did not cause significant complaints and serious hemodynamic disorders in the patient, but surgery was suggested. After repeated EVLA, the patient felt better, the varicose signs disappeared shortly after.

Conclusion
It is evident that EVLA with an energy density of 120-140 J/cm is effective in the treatment of varicose veins in patients with diabetes type 2. This effectiveness was demonstrated through improved quality of life indicators according to the VCSS assessment and a minimal number of recurrences post-surgery in patients with diabetes.

Future Research Prospects
Our future research plans include the development of methods aimed at preventing varicose vein relapses, thereby alleviating chronic venous symptoms and facilitating earlier patient rehabilitation.

References

Реферат
ЕФЕКТИВНІСТЬ ЩІЛЬНОСТІ ЕНЕРГІЇ 120-140 Дж/см ДЛЯ ЕНДОВЕНОЗНОЇ ЛАЗЕРНОЇ АБЛЯЦІЇ У ПАЦІЄНТІВ З ЦУКРОВИМ ДІАБЕТОМ
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Ключові слова: варикозне розширення вен, цукровий діабет, EVLA, густина енергії, результати.
Мета. Проаналізувати вплив енергії 120-140 Дж/см на ендовенозну лазерну абліацію у пацієнтів з цукровим діабетом. Матеріал та методи. Було проаналізовано результати лікування 40 пацієнтів з варикозною хворобою та цукровим діабетом як супутнім захворюванням. Серед них було 27 жінок (67,5%) та 13 чоловіків (32,5%). Середній вік пацієнтів склав 59.5±1.18 років, варіюючись від 44 до 74 років. Рівень глюкози у крові становив 184,5±11,6 ммоль/л, а концентрація гликогемоглобіну - 8,5±0,25%. Середня тривалість цукрового діабету в анамнезі становить 10,6±0,91 року. Для ендовенозної лазерної абліації застосовували діодний пристрій Biolitec ELVeS Radial 2 Ring Fiber та лазер з джерелом жиною хвилі 1470 нм та енергією 120 Дж/см.
Результати обстежень. Загальний бал VCSS для правої нижньої кінцівки склав: 4,75±0,725 – через 1 тиждень; 0,79±0,306 – через 6 місяців; 0,36±0,151 – через 1 рік; відповідно для лівої нижньої кінцівки 5,37±0,806 через 1 тиждень; 2,6±0,643 – через 1 місяць; 1,06±0,351 – через 6 місяців; 0,62±0,034 – через 1 рік. Через 1 тиждень після ендовенозної лазерної абліації спостерігалось інтенсивне зниження больового індексу в правій нижній кінцівці, а через 6 місяців він зменшився на 90% після ендовенозної лазерної абліації. Під час усіх спостережень інтенсивність болю була статистично значно менша, ніж при попередніх обстеженнях (р<0,05). У короткий термін після ендовенозної лазерної абліації швидше зменшувалося інтенсивність болю у лівої кінцівці, а також зниження симптомів хронічної венозної недостатності забезпечили більш ранню реабілітацію пацієнтів. Рецидив спостерігався у 1 випадку (2,5%). Висновки. Енергія 120-140 Дж/см була схвалена як оптимальна щільність для ендовенозної лазерної абліації у пацієнтів з варикознимі розширеннями вен і цукровим діабетом.