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Factors influencing the outcome of endovenous laser ablation of varicose veins. Six-year Czech experience.

Facteurs influençant les résultats de l'ablation des varices par laser endoveineux. Expérience tchèque de 6 ans.

Kaspar S., Tomesova I., Zichova J.

Résumé

Introduction : Il persiste encore beaucoup de controverses quant aux meilleurs paramètres à utiliser dans le traitement des varices par laser endoveineux. Plusieurs études ont montré que le succès de la procédure par laser endoveineux est énergie dépendante avec les meilleurs résultats pour une énergie importante mais jusqu'à ce jour il n'a pas été établi de protocole standardisé permettant de définir l'énergie exacte à délivrer. Basé sur nos propres études en laboratoire confirmant une meilleure rétraction de la veine à faible puissance, nous avons fait une analyse rétrospective de nos patients traités par laser endoveineux.
Matériel et méthode : Au total 673 procédures endoveineuses ont été pratiquées chez 605 patients présentant des varices des membres inférieurs. Tous les patients ont été examinés cliniquement et par échographie-Doppler. Les contrôles postopératoires (clinique, écho-Doppler, et des scléroses complémentaires si nécessaire) ont été pratiqués au 5e jour, à 1 mois, 6 mois et chaque année. Un laser à diode de 980 nm et un laser Nd : YAG de 1 320 nm ont été utilisés.
Les facteurs influençant la non-occlusion ou bien la recanalisation précoce et tardive ont été déterminés par l'analyse en régression de Cox. En utilisant la méthode de Kaplan-Meier, les résultats furent évalués en comparant la classification CEAP et le pourcentage de recanalisation, en pré- et postopératoire.
Résultats : Aucune thrombose veineuse ou embolie pulmonaire n'ont été diagnostiquées en postopératoire. Le suivi à long terme a été possible chez 98,7 % des membres traités. L'occlusion saphénienne à 1 mois a été de 95,7 % et la non-occlusion ou la recanalisation précoce de 4,3 % pour la même période. Au total 53 troncs saphéniens non occlus ont été retrouvés durant toute la période de l'étude (1-69 mois, avec une moyenne 20 mois) ce qui représente un taux final d'occlusion de 91,86 %. En utilisant l'analyse de Kaplan-Meier, on a retrouvé un taux d'occlusion de 86 %. La classification clinique CEAP, qui était en moyenne de 2,22 avant l'opération, s'est améliorée avec une moyenne de 0,24 à 1 mois et de 0,48 lors la dernière visite. L'analyse en régression de Cox à retrouvé 2 facteurs statistiquement significatifs : l'indice de masse corporelle (p = 0,047) et la faible puissance des paramètres de tir laser (p = 0.049). Le taux cumulé d'occlusion à 69 mois a été plus important (87,5 %) chez les patients avec un indice de masse corporelle < 25 comparé aux patients en surpoids (81 %) (test du log-rank : p = 0,043). Avec une puissance inférieure à 13 W, les résultats étaient significativement meilleurs (test de log-rank : p = 0,005) comparés à ceux avec une puissance égale ou supérieure à 13 W. La puissance moyenne était de 14 W dans le groupe de veines non occluses tandis que dans celui des troncs occlus elle était de 12W (p = 0,0095).
Conclusions : Cette étude établit le concept qu'une « cuisson » lente et douce des veines durant l'ablation par laser endoveineux permet d'obtenir un bon résultat à court et long terme.
Basé sur ces observations, nous recommandons une puissance faible ou moyenne (8 à 12 W) avec une vitesse de retrait de la fibre laser, lente (0,2 à 2 mm/s) pour obtenir l'énergie par centimètre nécessaire qui donnerait les meilleurs résultats cliniques avec le moins d'effets secondaires.

Mots clés : *laser endoveineux, résultat clinique, standardisation, énergie laser, puissance, effets secondaires.*

Summary

Background : *Many controversies still remain as to best parameters of the endovenous laser treatment of varicose veins. Higher energy dose improves procedural success but to date there is no standardized energy delivery protocol. Based on our experimental laboratory study confirming better shrinkage of the vein when lower power settings were used, we performed retroprospective clinical study of our patients operated on with endovenous laser.*
Material and Methods : *In total, 673 endovenous laser procedures of trunk varicose veins of lower extremities in 605 patients were analysed. Every patient was preoperatively examined clinically and using color duplex machine. Post-operative follow-up (clinical, duplex ultrasound and complementary sclerotherapy if needed) was performed 5 days after procedure, after 1 month, 6 months and yearly thereafter. Diode 980nm and Nd : YAG 1320nm lasers were used for endovenous ablation. Cox regression analysis was used to detect the factors influencing non-occlusion and early or late recanalisation of saphenous vein. The results were evaluated by the comparison of CEAP clinical class pre- and post-operatively, by the percentage of recanalizations and also using the Kaplan-Meier life-table method.*
Results : *No thrombosis, nor pulmonary embolism were diagnosed in the post-operative period. Postoperative data were available during different time periods in 98.7% of limbs. Saphenous occlusion was verified in 95.7% of limbs after 1 month, non-occlusion or early reopening was seen in 4.3% at this time. In total, 53 non-occluded saphenous trunk veins were found during the whole follow-up period (1-69 months, mean 20 months) which represents final occlusion rate of 91.86%. Using Kaplan-Meier analysis, we reached 86% occlusion rate. Mean clinical CEAP classification improved from 2.22 (before operation) to 0.24 (1 month after) and 0.48 (last visit). Cox regression analysis found 2 factors with statistical significance: body mass index (p = 0.047) and laser power (p = 0.049). Cumulative rate of occlusion in 69 month horizon is higher (87.5%) in patients with BMI < 25 compared to patients with overweight (81%), log-rank test: p = 0.043. Using power values less than 13W, the results were significantly better (log-rank test: p = 0.005) compared to power values of 13 W or more. Median power in non-occluded veins was 14W while in occluded trunks was 12W (p = 0.0095).*
Conclusions: *The present clinical study supports the concept of «slow and gentle heating» during the endovenous laser treatment to achieve good immediate and late result. Based on these observations we recommend lower or medium power settings (8 to 12 W) with slower pull-back speed of the laser fibre (0.2 to 2 mm/sec) to achieve sufficient energy per centimeter of the vein and the optimal clinical outcome with minimal side-effects.*

Keywords: endovenous laser, clinical outcome, standardization, laser energy, power, side-effects.

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Introduction

• Treatment of the refluxing great saphenous vein (GSV) or short saphenous vein (SSV) has traditionally been surgical ligation and stripping. Recently, endovenous thermal ablation procedures (radiofrequency and endovenous laser) have shown promising results. The aim of these methods is direct thermal injury to venous wall which results in contraction of the vessel with subsequent occlusion and fibrosis.

• However, many controversies still remain concerning the best parameters of the procedure and there is only limited available data on systematic experimental and mathematical evaluation of these methods [1, 2, 3, 4, 5, 6].

• The main parameter influencing outcome of the treatment seems to be delivered energy at the vein wall and according to some clinical studies [7, 8, 9, 10, 11], the higher energy dose improves procedural success. Nevertheless, to date there is no standardized energy delivery protocol and the parameters infuencing the clinical outcome are still to be determined. Based on our experimental laboratory observations [12], we performed retrospective clinical analysis of the group of our patients with truncal varicose veins operated on with endovenous laser during nearly 6 year period.

Material and Methods

• Six hundred and seventy three consecutive procedures performed in 605 patients in 6 year period were analysed. Incompetent trunks of GSV or SSV were irradiated with laser energy delivered continuously by the diode generator emitting 980 nm (BIOLITEC, CeramOptec GmbH, Bonn, Germany) or 1320 nm (CTEV, CoolTouch, Roseville, USA) laser beam under tumescent local anesthesia (TLA) and ultrasound guidance in the office surgical suite according to usual protocol [13]. Additional hook phlebectomies were performed in all cases. All patients received low molecular weight heparin (LMWH) during next 3 days. Post-procedural follow-up (clinical and duplex ultrasound) was accomplished after 5 days (D5), 1 month, 6 months and yearly thereafter.

• Cox regression analysis was used to detect factors concerning patients (age, gender, clinical class CEAP [Clinical, etiological, anatomical, and pathophysiological classification], BMI [body mass index], and comorbidities), their veins (length and diameter) and technical parameters of the procedure (total energy, energy per centimeter, total laser time, pull-back rate, and power) which could influence non-occlusion and early or late recanalisation of saphenous vein. Successful treatment was defined by the absence of flow in the treated vein segment by duplex ultrasoud imaging and the durability of saphenous occlusion was assessed by percentage of recanalisations and using Kaplan-Meier life-table method.

1.	To what extent did you experienced any limitations at work or in any other daily activities?
2.	Did you have any sleep-related difficulties regarding your operation?
3.	To what extent did you feel somewhat limited in remaining in a standing position?

*TABLEAU 1 : **Questions related to pain.***

• Clinical results were evaluated by comparison of clinical classification CEAP pre- and post-operatively.

Following our laboratory study [12] we selected procedures (n = 284) with linear endovenous energy density (LEED) ≥ 60 J/cm and without difference in demographic patient´s data, treated saphenous veins, number of additional phlebectomies and TLA volumes used. In this cohort, quality of life (QoL) evaluation (CIVIQ-2 questionnaire) [14] was performed. Furthermore at D5, 10-cm visual analogue scale (VAS) was used to compare post-operative pain by patient, and bruising or haematoma, fibrous cord formation and eventual superficial phlebitis by physician. All patients completed short pain related questionnaire **(Table 1)**.

Ethics

Institutional review board approval was obtained for this study.

Statistical analysis

Descriptive measures were used for analysis. Results are expressed in terms of median values with inter-quartile ranges. To compare the demographic data, laser parameters, clinical CEAP, QoL, post-operative pain, bruising, induration and phlebitis, non-parametric Mann-Whitney U-test was used. Kaplan-Meier life table method was used to evaluate the occlusion of GSV.

P value of 0.05 was considered significant. All analyses were performed using software Excel (Microsoft, Redmond, USA) and Statistica (version 8.0, StatSoft, Tulsa, USA).

Results

No thrombosis, nor pulmonary embolism were diagnosed in the post-operative period. Postoperative data were available during different time periods in 98.7% of limbs.

Saphenous occlusion was verified in 644 limbs (95.7 %) after 1 month, non-occlusion or early reopening was seen in 29 limbs (4.3 %) at this time.

Totally, 53 non-occluded saphenous trunk veins were found during the whole follow-up period (up to 69 months, mean 20 months) which represents final occlusion rate of 91.86 % **(Table 2)**.

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Duplex findings	1 month	Last visit (1-69 months)
Occluded	644 (95.7 %)	620 (91.86 %)
Non-occluded	29 (4.3 %)	53 (8.14 %)

TABLEAU 2 : Duplex GSV occlusion rate.

	BMI < 25	BMI ≥ 25
Number of procedures	540	133
Mean vein diameter (mm)	11,17	11,18
Mean energy (J/cm)	83,31	87,82
Male	145	30
Female	395	103
Age (years)	17-77	28-74

TABLEAU 3 : Data of patients according to their BMI.

	< 13 W	≥ 13 W
Mean vein diameter (mm)	11,54	11,70
Mean energy (J/cm)	97,34	105,77

TABLEAU 4 : Diameter of veins and laser energy according to power.

Using Kaplan-Meier analysis, we reached 86 % occlusion rate in the whole cohort (comprising learning period) during follow-up interval up to 6 years **(Figure 1)**.

Clinical CEAP classification improved from 2.22 (before operation) to 0.24 (1 month after) and 0.48 (last visit : 1-69 months).

Cox regression analysis selected 2 factors with statistical significance : body mass index (p = 0.047) and laser power (p = 0.049).

Data of patients according to their BMI is summarized in **Table 3**. Cumulative rate of occlusions in 69 month horizon is significantly higher - 87.5 % in patients with BMI < 25 compared to patients with overweight - 81 %, log-rank test : p = 0.043 **(Figure 2)**.

When comparing the influence of laser power on durability of saphenous occlusion in patients treated with LEED ≥ 60 J/cm (set as minimum to compare the influence of laser power on the occlusion), treshold of 13 W was set arbitrary based on median values in occluded and non-occluded veins.

Table 4 summarises the data of both cohorts. Using Kaplan-Meier survival method, the results of treatment with power < 13 W and ≥ 13 W were analysed. With power values < 13 W, results were significantly better (log-rank test : p = 0.005) compared to power values of 13 W or more **(Figure 3)**.

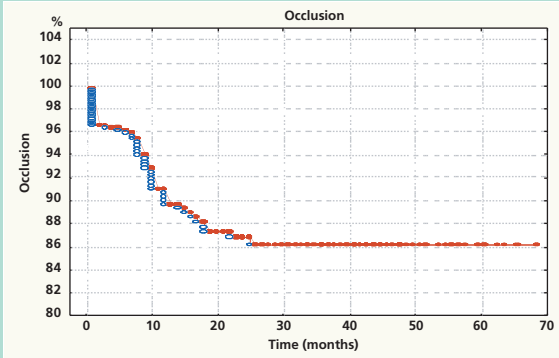

FIGURE 1 : Occlusion according to Kaplan-Meier - whole cohort.

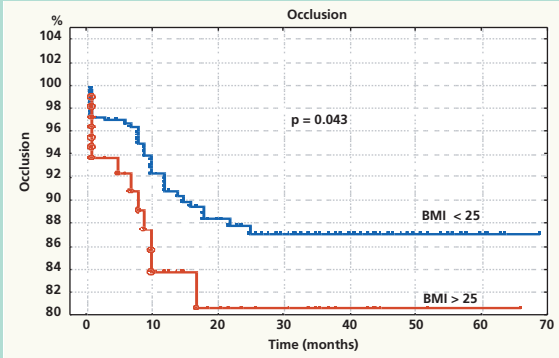

FIGURE 2 : Impact of body mass index on saphenous occlusion.

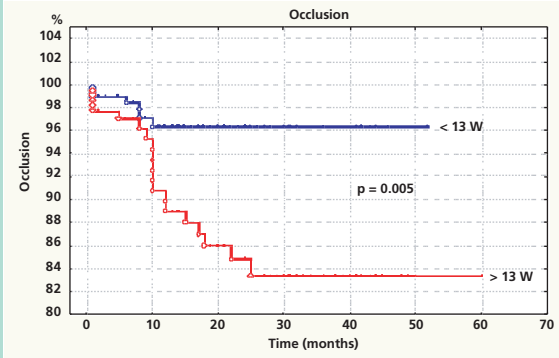

FIGURE 3 : Occlusion according to power (Kaplan-Meier).

Median power in non-occluded veins was 14 W while in occluded trunks 12 W **(Figure 4)**. This difference is statistically significant (p < 0.001).

Table 5 shows data of patients treated with 980 nm and 1320 nm lasers. The proportion of patients with overweight was higher using 1320 nm device however laser power was lower in 1320 nm group.

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	980 nm	1320 nm
BMI < 25	410 limbs	130 limbs
BMI ≥ 25	95 limbs	38 limbs
Power (W)	12,25	8,1

***TABLEAU 5 :** Data of patients treated with 980 nm and 1320 nm lasers.*

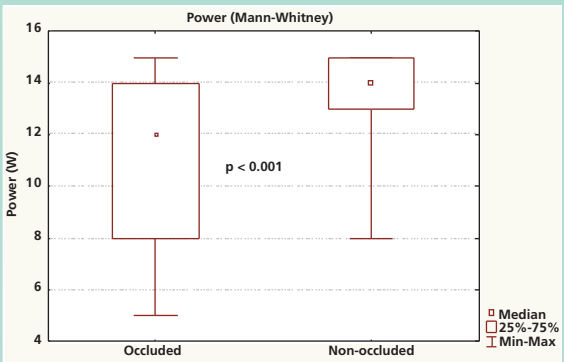

***FIGURE 4 :** Occlusion plotted against power (Mann-Whitney).*

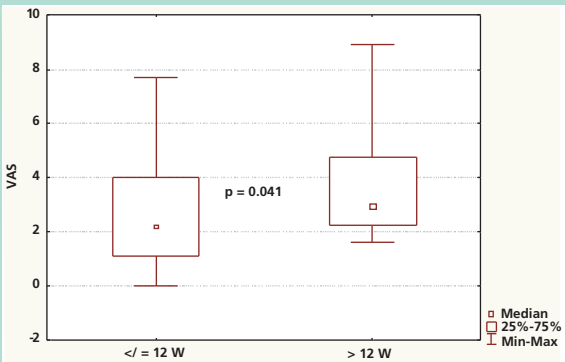

***FIGURE 5 :** Postprocedural pain evaluated by patient plotted against power.*

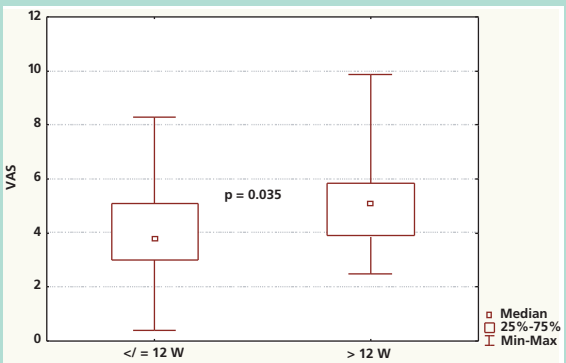

***FIGURE 6 :** Bruising evaluated by physician plotted against power.*

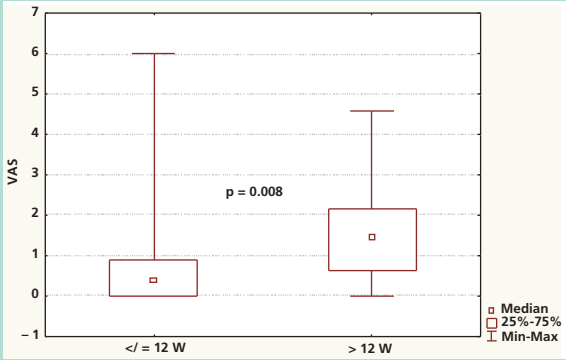

***FIGURE 7 :** Induration evaluated by physician plotted against power.*

• Immediate post-operative sequelae at D5 were significantly more favorable in lower power group (5 to 12 W) compared to 15 W group :

– pain (p = 0.041) : median [inter-quartile range] : 2.2 [1.1-4.0]) vs. 2.9 [2.25-4.75] **(Figure 5)** – bruising or hematoma (p = 0.035) : 3.8 [3.0-5.1] vs. 5.1 [3.9-5.85] **(Figure 6)** ;

– induration (p = 0.008) : 0.4 [0-0.9] vs. 1.45 [0.65-2.15] **(Figure 7)**.

• In both cohorts, no statistically significant difference was observed in terms of usual daily activities, sleep-related difficulties and prolonged standing position. The degree of phlebitis of GSV and eventual pain killer medication was same in both groups. QoL 1 month after procedure was also similar.

Discussion

• The amount of applied energy is of paramount importance during endovenous laser treatment. Undertreatment can result in a clinically unsatisfactory outcome, and overtreatment leads to adjacent tissue destruction without additional shrinkage and fibrosis of the targeted tissue. To establish the optimal parameters, it is necessary to determine the response of venous tissue to different thermal insults over different time periods. Furthermore, laser wavelength can also play an important role. One randomized and single-blinded study compared 810 nm and 980 nm diode lasers. Ecchymosis and superficial phlebitis was more often present when 810nm laser was used [15]. In order to minimize complications and side-effects, longer-wavelength lasers were developed [16].

• Some studies have recommended application of higher power (30 W) in order to administer high amount of laser energy to the venous wall [17, 18].

• In other studies [19, 20, 21], satisfactory outcome with low rate of complications and side effects was obtained by using quite low amounts of diode laser energy (35-39 J/cm) and power (11-12 W).

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• **The results of our study showed that the clinical outcome does not improve by using higher laser power (15 W).** Moreover, using this power setting might amplify the deleterious effect of the thermal laser treatment without increasing the therapeutic effect. Higher power produces substantial carbonisation of the fiber tip with additional temperature elevation and possible wall perforation. Higher power can also result in desintegration of the fiber tip due to carbonisation process. The current study showed significantly higher rate of side-effects for 15 W power group compared to lower power groups.

• Not only the total amount of energy per centimeter of vein length (LEED) can influence the final result but also the energy deposition pattern. **We found that "slow" heating using a low or medium power (8 to 12 W) with slow pull-back speed of 0.2 to 2 mm/sec lead to the best outcome** with minimum complications.

Conclusions

Based on our observations, we recommend low or medium power settings (8 to 12 W) with slower pull-back speed of laser fibre to achieve sufficient energy per centimeter of the vein and the optimal clinical outcome with minimal side-effects. Theoretical danger of prolonged heating of surrounding tissues can be successfully managed with ultrasound guided tumescence.

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