Outcomes of different laser power used in endovenous laser ablation of varicose veins

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Background
Endovenous laser ablation (EVLA) is of no standardized settings, particularly the laser power that remains under question.
Objective
To assess the safest power of laser with maximal effect and least complications in ablation of varicose veins.
Patients and methods
A prospective observational randomized study inducing EVLA of different laser power settings (7 and 10 W) with preoperative assessment, then follow-up by CEAP [classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)] and venous clinical severity score (VCSS), and duplex ultrasound as well as postoperative complications.
Results
This study included 50 patients (52 limbs). Preoperative complaint was mainly in the form of pain on standing and prominent varicosities. The patients were distributed as regards laser power used into two groups (7, 10 W) of 26 limbs for each one. There was a significant difference ($P<0.05$) between both groups of patients as regards VCSS after 3 months being better in the 10 W group. As regards great saphenous vein measure changes, there was a high significant difference ($P<0.001$) between those exposed to laser power 7 W in comparison with those of 10 W at 1- and 3 months follow-up in relation to preoperative measures showing more reduction in the 7 W group. Statistically, there was no significant difference between 7 and 10 W groups as regards time to return to work, CEAP [classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)] scores, and postoperative complications, except significant differences in pain over the treated vein being less in the 7-W laser power group.
Conclusion
About 10-W laser power of EVLA was associated with better postoperative VCSSs, despite different power settings were not affecting time of return to work and other postoperative complications apart from less pain over treated veins with 7-W laser power. We call for further studies of large size and long follow-up due to few available related studies.

Keywords:
endovenous laser ablation, laser power, varicose veins

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Introduction

Varicose veins of the leg are signs of chronic venous disease, which affect around 25–40% of the adult population. The aim of treatment is to reduce symptoms, but also to prevent long-term complications of chronic venous insufficiency such as leg ulceration [1].

Traditional treatment of varicose veins includes making lifestyle modifications, wearing compression stockings, and taking some medications. If these traditional treatments are not successful, endovascular procedures or surgery is recommended. Catheter-directed (endovascular) techniques have revolutionized the treatment of varicose veins, with reduced complications and time away from work [2].

In the past, flush ligation and stripping of incompetent saphenous veins have been recognized as the treatment of choice. Recently, endovenous procedures like radiofrequency, endovenous laser ablation (EVLA), and foam sclerotherapy have expanded the range of treatment modalities [3].

EVLA is a minimally invasive treatment for varicose veins, which eliminates reflux from the saphenofemoral junction (SFJ) or saphenopopliteal junction and the associated axial vein as great saphenous vein (GSV) and small saphenous vein by selective ablation of the highest point of 'deep to superficial' incompetent veins. Previous studies found that ablation is achieved in 88–100% of limbs [4].

In contrast to radiofrequency ablation, EVLA is not a standardized procedure, and can be used in many different settings. The mechanism of EVLA is not exactly known but is mainly based on heat transfer from the fiber tip to surrounding tissue by direct contact, heat conduction, and/or generation of steam bubbles. Currently, in the available options, the optimal effective EVLA devices or (power) settings remain under question, as regards efficacy [5].

The aim of this study was to assess the safest power of laser that gives maximal effect and least complications in EVLA of varicose veins.

Patients and methods

(1) Type of study: prospective observational randomized study.
(2) Study setting: Ain Shams University Hospitals and Alagouza Police Hospital.
(3) Study period: from December 2019 to July 2021.
(4) Study population.

Inclusion criteria

Patients complaining of varicose veins (swelling, pain, and heaviness on standing relieved by leg elevation) in one limb or both lower limbs with duplex ultrasound finding: incompetent GSV defined as reflux of more than 0.5 s and no history of interventions and GSV diameter more than 3 mm with reflux.

Exclusion criteria

(1) Alternatively, patients with GSV of more than 2 cm in diameter, acute deep vein thrombosis or superficial vein thrombosis, and a number of other conditions, including pregnancy, limited mobility, and arterial insufficiency, were excluded.
(2) Patients have past history of recent surgery.
(3) History of deep vein thrombosis.
(4) Patient has venous ulcer or other venous complications.
(5) Sampling method: convenience sample method.
(6) Sample size: 50 patients.

Ethical considerations: study procedures

This study was done after approval of the ethical committee. Informed consent was taken from all participants before recruitment in the study and after explaining the purpose and procedures of the study.

All patients will be subjected to the following:

(1) History taking.
(2) Clinical examination: including duplex ultrasound scanning and CEAP [classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)] and venous clinical severity score (VCSS) classifications.

Technique of the procedure

(1) The procedure was performed using tumescent anesthesia (combination of 40 ml of 1% lidocaine, 10 ml of sodium bicarbonate, and 450 ml of normal saline) administered subcutaneously and inducing tumescence along the segment of vein undergoing EVLA. Monitored anesthesia care sedation (midazolam 0.02 mg/kg and remifentanil 0.025 μg/kg/min) was delivered during the procedure.
(2) EVLA was performed with percutaneous access to the GSV using a diode laser (ELVeS Radial fiber, Food and Drug Administration (FDA)-certified; wavelength, 1470 nm). An FDA-approved endovenous laser kit was employed, consisting in a 21-G needle, a 6-Fr sheath, and a centimeter scale 150-cm-length catheter.
(3) The patient was initially positioned in the lateral decubitus position (anti-Trendelenburg) to facilitate cannulation of the GSV. Subsequently, EVLA was performed on the patient lying in the horizontal position without inclination.
(4) During the procedure, using a continuous retraction protocol, the energy dose (in J) was recorded as the probe passed from one segment to the next. As guided by the centimeter scale or the acoustic signal, the operator was able to accurately adjust the pullback speed.
(5) Under our protocol, 100 J/cm were delivered empirically to the first 3 cm distal to the SFJ (to be sure that collapse is locally very effective), thus providing 300 J in this first segment. In the underlying segments, the dose was diminished empirically to 80 J/cm.
(6) In this study, patients were randomized into two groups using simple randomization method, shuffled deck of cards (even = 7 W group, odd = 10 W group), one group was treated with

7-W laser power and the other was offered 10-W laser power and then follow-up of vein wall damage and occlusion rate.
(7) Following EVLA, compressive stocking 20–25 mmHg was prescribed for 4 weeks.
(8) The recommended analgesic therapy was paracetamol 1 g as needed (up to 3 g per day).

After 1 week, 1- and 3-month patients were followed up, where a clinical examination (CEAP and VCSS) and duplex ultrasound scanning of the operated limb was performed, including measurement of GSV diameter and reflux. Follow-up of postoperative complications and management of complications inside the hospital if occurring (infection, pain over the vein, bleeding, bruising, nerve damage, inflammation of the vein, blood clots, and changes in skin color over the treated vein).

Statistical analysis

Recorded data were analyzed using the Statistical Package for Social Sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean±SD. Qualitative data were expressed as frequency and percentage.

The following tests were done:

(1) Paired-sample *t* test of significance was used when comparing between the related sample.
(2) Independent-samples *t* test of significance was used when comparing between two means.
(3) χ^2 test of significance was used in order to compare proportions between qualitative parameters.
(4) The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *P* value was considered significant as the following:
(5) *P* value:
   (a) *P* value less than 0.05 was considered significant.
   (b) *P* value less than 0.001 was considered as highly significant.
   (c) *P* value more than 0.05 was considered insignificant.

Results

It is a prospective observational study, including 50 patients (52 limbs, 48 cases were unilateral while bilateral in two cases, affecting the right side in 30 cases and left side in 22 cases) who underwent EVLA, 35 females and 15 males, age range 19–58 years (mean, 38.14±10.44). Preoperative complaint was mainly in the form of pain on standing and prominent varicosities as shown in Table 1. Preoperative CEAP is described in detail in Table 2.

The patients were equally distributed as regards laser power doses used into two groups (7, 10 W) of 26 limbs for each one. Postintervention after 1 and 3 months as described in Table 3, Table 4, and Table 5, respectively, there were statistically highly significant changes ($P<0.001$) in preoperative mean great saphenous diameter (as decreased from 7.00±1.43 preoperatively to 2.84±0.71 after 1 month and 1.25±0.34 after 3 months), CEAP, and mean VCSS (as changed from 5.77±1.11 preoperatively to 2.38±0.72 and 0.67±0.61 after 1 and 3 months, respectively).

Patients showed marked improvement of their complaint in 1-week postoperative follow-up (as out of 52 treated limbs, five patients were still complaining of pain, 12 patients with swelling, and 21 patients still complaining of limb edema) with return to work range that was 2–4 weeks (mean 2.58±0.61), most of the patients were without complications ($P<0.001$) as shown in Table 6 and Table 7, respectively, while postoperative complications were about skin inflammation in nine (17.3%) cases, pain over the vein in eight (15.4%) cases, ecchymosis in seven (13.5%) cases, and thrombophlebitis in four (7.7%) cases.

Table 1 Preoperative complaint distribution among study group (*N*=52)

Complaint	Total [*n* (%)]
Pain	52 (100.0)
Swelling	44 (84.6)
Edema	38 (73.1)
Ulceration	1 (1.9)
Pigmentation	1 (1.9)

Table 2 Preoperative CEAP distribution among study group (*N*=52)

Preoperative CEAP	Total [*n* (%)]
C	
2	13 (25.0)
3	38 (73.1)
5	1 (1.9)
E	
P	52 (100.0)
A	
S2	4 (7.7)
S3	48 (92.3)
P	
R	52 (100.0)

CEAP, classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P).

Table 3 Comparison between preoperative great saphenous vein and other measurements 'after 1 month and after 3 months' in patients' group

			Paired-sample *t* test		
GSV	Range	Mean±SD	MD±SE	*t* test	*P* value
Preoperative	4–11	7.00±1.43			
After 1 month	1.5–5	2.84±0.71	4.16±0.14	29.805	<0.001**
After 3 months	1–2.5	1.25±0.34	5.75±0.17	34.178	<0.001**

GSV, great saphenous vein; MD, mean difference. ****P** value less than 0.001 is highly significant.

Table 4 Comparison between preoperative, after 1 month and after 3 months according to CEAP in patients' group

CEAP	Preoperative (*N*=52) [*n* (%)]	After 1 month (*N*=52) [*n* (%)]	After 3 months (*N*=52) [*n* (%)]	χ^2	*P* value
1	0	43 (82.7)	49 (94.2)		
2	13 (25.0)	9 (17.3)	3 (5.8)		
3	38 (73.1)	0	0	130.667	<0.001**
4	0	0	0		
5	1 (1.9)	0	0		

Using χ^2 test. CEAP, classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P). ****P** value less than 0.001 is highly significant.

Table 5 Comparison between preoperative venous clinical severity score and other measurements 'after 1 month and after 3 months' in patients' group

			Paired-sample *t* test		
VCSS	Range	Mean±SD	MD±SE	*t* test	*P* value
Preoperative	3–10	5.77±1.11			
After 1 month	0–4	2.38±0.72	3.38±0.13	25.614	<0.001**
After 3 months	0–2	0.67±0.61	5.10±0.17	29.617	<0.001**

MD, mean difference; VCSS, venous clinical severity score. ****P** value less than 0.001 is highly significant.

Table 6 Complaint distribution among study group at follow-up 1 week

Complaint	Partial complaint [*n* (%)]	Still complaint [*n* (%)]	No complaint [*n* (%)]	Total *N*
Pain	21 (40.4)	5 (9.6)	26 (50.0)	52
Swelling	19 (43.2)	12 (27.3)	13 (29.5)	44
Edema	17 (44.7)	21 (55.3)	0	38
Ulceration	0	1 (100.0)	0	1
Pigmentation	0	1 (100.0)	0	1

Table 7 Comparison with and without complications of postoperative according to time to return to work

Time to return to work (weeks)	Without complications (*N*=37) [*n* (%)]	With complications (*N*=15) [*n*. (%)]	χ^2	*P* value
2 weeks	23 (62.2)	2 (13.3)		
3 weeks	14 (37.8)	10 (66.7)	14.615	<0.001**
4 weeks	0	3 (20.0)		

Using χ^2 test. ****P** value less than 0.001 is highly significant.

In subgroups analysis between patients who offered 7 or 10 W power of laser, there was significant difference ($P<0.05$) between both groups of patients as regards VCSS after 3 months being better in the 10 W group (mean VCSS in 7 W group 0.92±0.80, mean VCSS in 10 W group 0.42±0.38) in contrast to insignificant difference after 1 month as described in Table 8, Fig. 1.

As regards GSV measure changes, there was high significant difference ($P<0.001$) between those exposed to laser power 7 W in comparison with those of 10 W at 1- and 3-month follow-up in relation to preoperative measures showing more reduction in the 7 W group (mean GSV diameter in 7 W group 1.06±0.16, mean GSV diameter in 10 W group 1.44±0.36 after 3 months) as shown in Table 9 and Fig. 2.

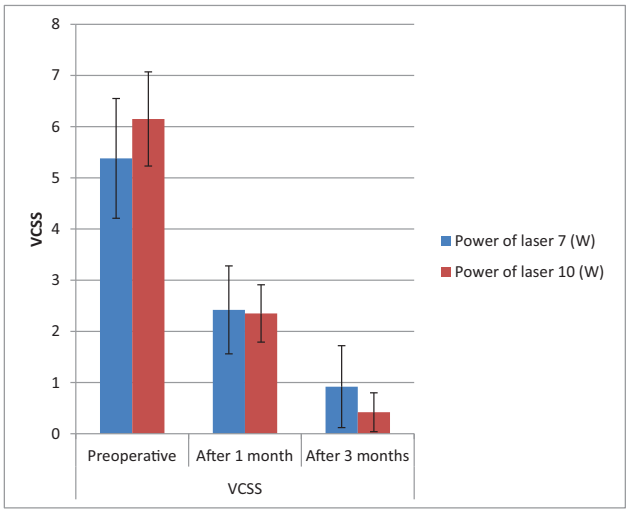
Statistically, there was no significant difference between 7 and 10 W groups as regards time to

Table 8 Comparison power of laser (7 and 10 W) according to venous clinical severity score

VCSS	Power of laser (W) 7 W Mean±SD	10 W Mean±SD	*t* test	*P* value
Preoperative	5.38±1.17	6.15±0.92	−2.632	0.011*
After 1 month	2.42±0.86	2.35±0.56	0.383	0.703
After 3 months	0.92±0.80	0.42±0.38	2.706	0.009*

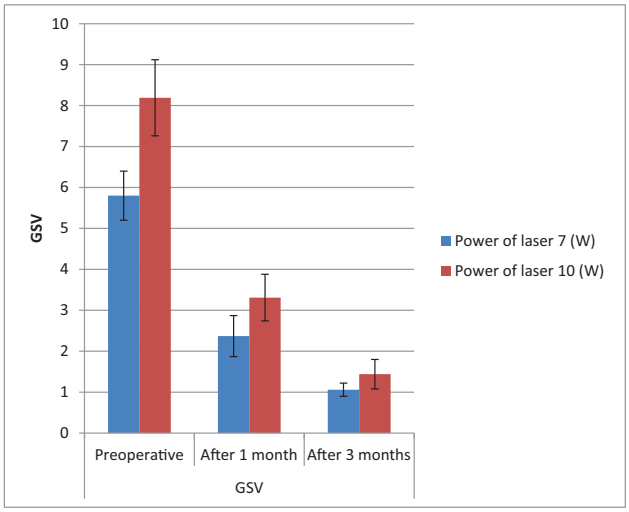
Using *t* independent sample *t* test. VCSS, venous clinical severity score. *P* value more than 0.05 is insignificant. **P* value less than 0.05 is significant.

Figure 1



Comparison power of laser (7 and 10 W) according to VCSS. VCSS, venous clinical severity score.

Figure 2



Comparison power of laser (7 and 10 W) according to GSV. GSV, great saphenous vein.

return to work as described in Table 10. On analyzing the postoperative complications, there was

Table 9 Comparison power of laser (7 and 10 W) according to great saphenous vein

GSV	Power of laser (W) 7 W Mean±SD	10 W Mean±SD	*t* test	*P* value
Preoperative	5.80±0.60	8.19±0.93	−11.000	<0.001**
After 1 month	2.37±0.50	3.31±0.57	−6.349	<0.001**
After 3 months	1.06±0.16	1.44±0.36	−5.013	<0.001**

Using *t* independent sample *t* test. GSV, great saphenous vein. *P* value more than 0.05 is insignificant. **P* value less than 0.05 is significant.

Table 10 Comparison power of laser (7 and 10 W) according to time to return to work in weeks

Time to return to work (weeks)	Power of laser (W) 7 [*n* (%)]	10 [*n* (%)]	χ^2	*P* value
2 weeks	15 (57.7)	10 (38.5)		
3 weeks	10 (38.5)	14 (53.8)	2.000	0.368
4 weeks	1 (3.8)	2 (7.7)		
Total	26 (100.0)	26 (100.0)		

Using χ^2 test. *P* value more than 0.05 is insignificant.

Table 11 Comparison power of laser (7 and 10 W) according to overall complications

Complications	Power of laser (W) 7 [*n* (%)]	10 [*n* (%)]	χ^2	*P* value
Pain over the vein	19 (73.1)	25 (96.2)	5.318	0.021*
Inflammation	7 (26.9)	2 (7.7)	3.359	0.067
Ecchymosis	5 (19.2)	2 (7.7)	1.486	0.223
Thrombophlebitis	1 (3.8)	3 (11.5)	1.083	0.298
Overall complications	10 (38.5)	5 (19.2)	2.342	0.126

Using χ^2 test. *P* value more than 0.05 is insignificant.

insignificant difference between 7 and 10 W groups, except in pain over the treated vein, there was significant difference being less in patients who exposed to 7-W laser power, as found in Table 11 and Fig. 3.

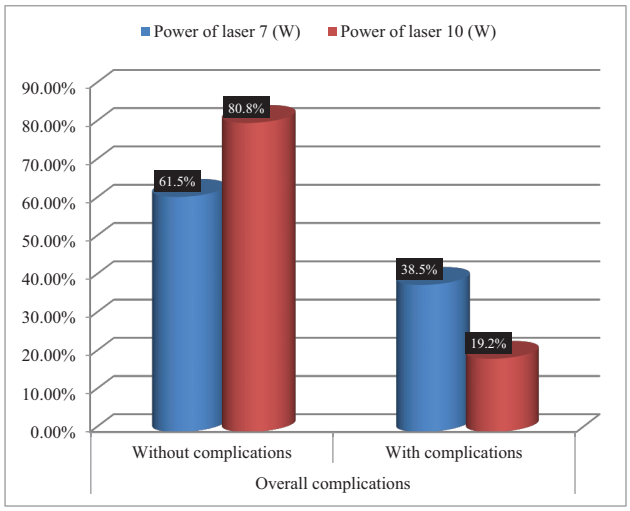
As regards CEAP scores, despite that there was a statistically high significant change ($P<0.001$) reported in all patients enrolled, there was no significant difference between 7 and 10 W groups as described in Tables 12 and 13 and Fig. 4.

Discussion

As EVLA still has no standardized parameters and can be used in many different settings, the optimal effective settings, particularly the laser power, remain under question [5].

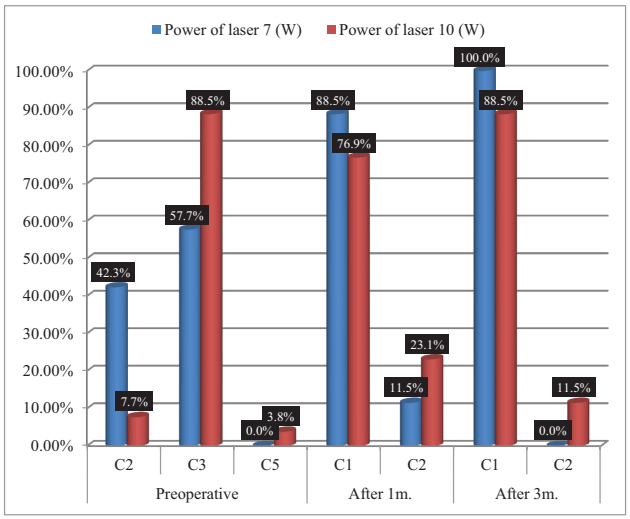
During systematic review and meta-analysis of 28 randomized control trails conducted from 2005 to

Figure 3



Comparison power of laser (7 and 10 W) according to overall complications.

Figure 4



Comparison power of laser (7 and 10 W) according to CEAP. CEAP, classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P).

Table 12 Comparison between preoperative, after 1 month and after 3 months according to CEAP in patients' group among power of laser at 7 W)

CEAP	Preoperative (*N*=26)	After 1 months (*N*=26)	After 3 months (*N*=26)	χ^2	*P* value
1	0	23 (88.5)	26 (100.0)		
2	11 (42.3)	3 (11.5)	0		
3	15 (57.7)	0	0	68.633	<0.001**
4	0	0	0		
5	0	0	0		

Using χ^2 test. CEAP, classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P).
***P* value less than 0.001 is highly significant.

Table 13 Comparison between preoperative, after 1 month and after 3 month according to CEAP in patients' group among power of laser at 10 W

CEAP	Preoperative (*N*=26)	After 1 month (*N*=26)	After 3 months (*n*=26)	χ^2	*P* value
1	0	20 (76.9)	23 (88.5)		
2	2 (7.7)	6 (23.1)	3 (11.5)		
3	23 (88.5)	0	0	72.178	<0.001**
4	0	0	0		
5	1 (3.8)	0	0		

Using χ^2 test. CEAP, classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P).
***P* value less than 0.001 is highly significant.

2017 by Malskat *et al.* [5], they found that wavelength-administered energy of EVLA does not influence the success rate of such treatment, but they did not clarify the effect of laser power settings on outcomes as regards clinical presentation or duplex findings.

In our study, taking into consideration that we used diode laser of 1470-nm wavelength, all patients showed significant improvement in clinical scores such as CEAP and VCSS, which associated with significant reduction of mean GSV diameter throughout 1- and 3-month postoperative follow-up, but these findings were analyzed trying to find the effect of laser power on patients' outcomes, as there are few studies focused on this parameter.

Our patients, who offered 10-W laser power of EVLA, presented with better reduction of VCSS of statistical significance after 3 months of postoperative follow-up in comparison with those treated by EVLA of 7-W laser power. In contrast to that, Araujo *et al.* [6] studied the effect of low (10 W) versus high (17 W) power of EVLA of 1470-nm laser over 1 year and found that there was no significant difference between both groups as regards VCSS in comparison with each other, despite that there was significant reduction of VCSS in both groups separately.

As regards CEAP scores, in our study, EVLA of 7-W and 10-W laser power did not show any difference preoperatively versus 1 and 3 months postoperatively. This finding is supported with a study conducted by Maurins *et al.* [3] who compared the effect of 17 versus 27 W of 1470-nm laser of EVLA results, which showed no significant difference between both groups as regards modified CEAP clinical severity score.

During our study, there was statistically high significant reduction of GSV measures in patients treated with EVLA of 7 W power at 1- and 3-month observations when compared with those of 10-W EVLA patients. On the other hand, Araujo *et al.* [6] found no significant difference between both groups as regards change in mean SFJ diameter in comparison with each other with significant reduction in SFJ diameter in both groups separately. The same impression was when Maurins *et al.* [3] compared the effect of 17 versus 27 W of 1470-nm laser of EVLA results, which found that there was no significant difference between both groups as regards GSV diameter reduction.

Šikovec [7] studied the outcomes of Nd : YAG 1064-nm laser using two different power settings over 2.5 years in treatment of 525 legs. In total, 102 legs offered 15–18 W of average power with 94% of them remaining occluded after 6 months and 88.2% remained occluded after 1 year, while 423 legs offered 25-W power with 99.2% of them remaining occluded after 6 months and 98.5% remained occluded after 1 year.

Proebstle and colleagues studied the effect of increased laser energy dosing on recanalization rates after EVLA of GSV using either 17 or 30 W laser power 940-nm diode laser and found that GSV occlusion rates for 17 and 30 W groups were 90.4 and 100% at 3 months, 82.7 and 97% at 1-year follow-up, respectively, which considered a statistically significant difference according to the method of Kaplan and Meier (log-rank, P=0.001), concluding that laser energy with higher dosing showed a significant reduction of recanalization rates throughout 12 months' observation [8].

Based on a previous study conducted at the Clinic of Phlebology and Laser Surgery, Chelyabinsk, Russia and Department of Surgery, South Ural State Medical University, Chelyabinsk, Russia, which found that using increasing laser power from 7 to 10 W of around 70 J/cm linear endovenous energy density, was associated with more venous wall damage of a significant statistical difference. Borsuk [9] presented, at the International Union of Phlebology held on August 2019, the results of a randomized controlled trial throughout 6 months' observations and concluded that there was no significant difference in pain and recanalization rates for patients undergoing EVLA at different power doses.

Most of our study patients found to be without postoperative complications, which was reflected in the short time of recovery and early return to work. With no influence of laser power on the time to return to work and postoperative complications, except the pain over treated vein as was significantly less in patients treated with 7-W laser power in comparison with those with 10-W laser power.

These findings are comparable to those of a study performed by Maurins *et al.* [3] who found no significant difference between both groups as regards return to daily activities with less postinterventional pain in lower power group. A previous study conducted by Šikovec [7] using two different power doses (17–18 W and 27 W) with minimal side effects postoperatively, most of them were mild skin irritation and ecchymosis but of no difference between both groups.

In contrast to that, Proebstle *et al.* [10] found a statistically significant difference in side effects between three groups (940 nm 17 W, 940 nm 30 W, and 1320 nm 8 W) being less in the lowest power group. Because of the differences in both wavelength and power, these findings are difficult to apply.

Chang and Chua studied the effect of 17 W 1064-nm laser power with ligation of SFJ over 252 legs of 149 patients treated over 4 years with resultant ablation of varicosities of 96.8% of patients after 6 months of intervention. Complications were minimal, mainly ecchymosis, and most of them disappeared at 6 months with no side effects at 28 months [11].

Because of the relatively short time frame and some patients' refusal of participation, our study limitations were the relatively small number of patients included and we need a longer follow-up data of our patients with expected significant changes in occlusion rates and recurrence. The longer follow-up of these patients will be our next project to test the outcomes after 1 and 2 years.

Conclusion

About 10-W laser power of EVLA was associated with better postoperative VCSSs, despite different power settings were not affecting time of return to work and other postoperative complications apart from less pain over treated veins with 7-W laser power. We call for further studies of large size and long follow-up due to few available related studies.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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