

Life Style and Outcome Assessment of Radiofrequency Versus Endovenous Laser Ablation in Management of Varicose Veins, a Comparative Study

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ABSTRACT

Introduction: The lower limbs are frequently affected by varicose veins (VVs), which are dilated, convoluted veins. In order to manage VVs, conventional surgery proved difficult, and endovenous procedures like radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) have lately taken its place.

Objective: This study investigated the effects of RFA compared with EVLA in treating VVs in terms of patient satisfaction and postoperative complications.

Methods: Seventy patients with lower limb primary VV were enrolled in this multicenter interventional prospective randomised controlled trial, which took place at three tertiary institutions between January and September of 2023. Two groups—the RFA group and the EVLA group—were randomly assigned to each patient. Post-operative conditions were estimated using the Villata score, and post-operative success, complications, and recurrence were evaluated.

Results: The average age of the cases in the RFA group and EVLA groups was 36.51 ± 7.25 and 37.63 ± 7.48 years, respectively. Hyperpigmentation showed a significantly higher level in the RFA group. Both groups had almost the same immediate and delayed success rate, between 96% and 98%. Recurrence rates during follow-up showed no statistically significant difference. The overall Villalta score, as well as its domains and pain distributions among the study participants, did not show a significant difference between the RFA and the EVLA, where both groups show significant enhancement.

Conclusion: RFA and LA improve pain and life quality similarly in patients with VVs, making them a first choice in treating primary varicose veins.

Key Words: Endovenous laser ablation, radiofrequency, varicose veins, villalta.

Received: 19 February 2025, **Accepted:** 12 March 2025, **Published:** 1 October 2025

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ISSN: 1110-1121, October 2025, Vol. 44, No. 4: 1137-1145, © The Egyptian Journal of Surgery

INTRODUCTION

The lower limbs are frequently affected by varicose veins (VVs), which are defined as convoluted and dilated veins^[1]. Up to 30% of the general population may be affected by them^[2]. In addition to being unsightly, VVs can result in thrombophlebitis or superficial venous thrombosis (SVT), venous leg ulcers (VLU), discomfort, swelling, ankle skin damage, and/or bleeding^[3].

Depending on the patient's choices and symptoms, VVs can be treated non-surgically or surgically. The development of less invasive endovascular procedures has led to a notable improvement in treatment approaches for symptomatic VVs in recent years^[4]. Novel approaches to treating VV have developed during the past 20 years, and they all depend on ultrasonography. It became difficult to do conventional surgery^[5].

General anaesthesia is not required for these procedures. Because they are one-day operations, they also result in a speedier return to regular activities without the danger of wound infection^[6].

One endoluminal technique that has become a standard part of the treatment of VVs is endovenous thermal vein ablation^[7]. High levels of safety, pleasure, and efficacy define it. Among the most popular endovenous techniques are radiofrequency ablation (RFA) and endovenous laser ablation (EVLA)^[7].

RFA is an outpatient treatment that may be performed under local anaesthesia. Depending on the surgeon's preference and the results of the preoperative evaluation, each patient will receive a unique surgical treatment plan for their lower leg VV^[8].

A percutaneous technique called EVLA is used to ablate superficial veins that cannot sustain laser light. The axial veins, which include the great saphenous vein (GSV), short saphenous vein (SSV), and accessory saphenous veins (ASVs), are the primary target of this treatment^[9-10].

The purpose of this study is to better control and reduce the problems of VV (bleeding, venous ulcers, and cosmetic deformity) by comparing the effects of RFA and endovenous LA in treating VVs with relation to patient satisfaction and postoperative complications.

PATIENTS AND METHODS

This is an interventional prospective randomized controlled comparative study that included 70 patients diagnosed with lower limbs VV. The study was conducted at three tertiary hospitals from January 2023 to September 2023. It included patients from both sexes, aged 20 to 50 years, with primary VV, having body mass index between 18.5 and 30, and with patent and compressible deep veins with incompetent SFJ and/or SPJ. The study excluded patients with a history of DVT, those with secondary VV, highly tortuous VVs, veins diameter more than 20mm, peripheral vascular disease, and pregnant ladies.

This work compared radiofrequency and laser ablation in treating lower limb VV with regard to postoperative pain, venous thromboembolism, skin burning, and the recurrence rate.

Sample size:

The POWER and Sample program was used to calculate the sample size based on evidence from Mohamed N. *et al.*, (2022), where the proportion of thrombophlebitis in the RFA group is 50% while the EVLA is 8%. Assuming 95% power, Type I error 0.05, the Minimum required sample size is 27 patients in the RFA approach and 27 patients in the EVLA approach. After adding 30% for the dropout rate, the actual minimum sample size is 35 patients in the RFA approach and 35 patients in EVLA. Therefore, the total needed sample was 70 patients with varicose veins.

Ethical consideration: The institutional Ethical Research Committee examined and approved the study protocol (Code: 294). The participants were given a thorough explanation of the study's methodology and purpose. After informing the participants of the procedure's benefits and drawbacks, their informed permission was obtained prior to their enrolment in the research. Participation was completely optional, and the individual was able to leave the research at any time. All phases of data collection, entry, and analysis were carried out in a very private and confidential way in compliance with the Declaration of Helsinki.

Two equal groups of 35 research participants were randomly allocated to each group. Thirty-five patients in Group A had venous duplex postoperative monitoring.

The patients' complete medical and surgical histories, as well as demographic information, were taken, with a focus on identifying risk factors such prolonged standing, multiparous women, and a family history of VVs.

Additionally, they had a thorough clinical examination that included lower limb inspection and palpation as well as the Trendelenburg test to assess the competence of the superficial and deep venous valves in patients with varicose veins.

Standard laboratory tests were performed, including coagulation profile (PT, PTT, INR), lipid profile, haemoglobin, white cell count, platelet count, and HbA1c.

To assess the saphenofemoral junction's competency, the valves' competency, the veins' diameter, and the deep venous system's patency, a duplex of the lower limb veins was carried out.

Intraoperative procedure:

A 6F sheath was placed after a venous puncture under local anaesthesia, either in the great or short saphenous veins, guided by ultrasonography. The blood backflow was monitored to ensure the sheath was in place and prevent extravasation.

To ensure that the catheter was intravenous and in the intended vein, it was carefully inserted into the vein and its tip was constantly examined. To prevent ablation of the deep veins and DVT, the catheter was inserted till the saphenofemoral junction or the saphenopopliteal junction, leaving a 2cm gap between the tip of the catheter and the junction. After that, an ultrasound was performed for confirmation.

Ultrasound-guided instillation of tumescent anesthesia percutaneously was performed beneath the saphenous fascia to enhance the connection between the radiofrequency catheter and the vein wall by decreasing the luminal diameter of the vein., insulate the skin, and avoid postoperative burn. It is also used as a local anesthesia.

Through the use of a thermal generator, energy is consistently delivered at 120c during radiofrequency ablation, conducted at a power of 40W for each 7cm. In contrast, during laser ablation, the energy from a 1470nm laser is specifically absorbed by the intracellular water found in the vein wall as well as by the water content in the blood. Then patency of the deep system was checked with duplex ultrasound.

Removal of the sheath and good compression after removal of the catheter and checking complete ablation of

the affected vein was done. A compression bandage was applied to the affected limb, and the patient was urged to begin walking as soon as he was capable. The patients used the compression stockings for a duration of fifteen days and were given an antibiotic, a non-steroidal anti-inflammatory medication, and a venoactive medication during the recovery period after surgery.

Postoperative follow-up:

Postoperative follow-ups for patients were conducted for three hours, seven days, and the first and sixth months following surgery. A crepe bandage was applied to the whole leg and replaced by appropriately sized graduated compression stockings.

Duplex ultrasonography was conducted one month and again six months after the surgery, to detect recurrence rates and to make sure that the veins had been totally ablated and occluded and to detect thrombophlebitis, patients were registered to Villalta score with measurement of post-operative pain and self-satisfaction a Visual Analogue Scale (VAS)^[11]. Quality of life after surgery was assessed using the Arabic Egyptian version of the short Form 36 health survey questionnaire^[12].

Statistical methods:

SPSS (Statistical Package for Social Science) version 25.0 for Windows (IBM®, SPSS, Chicago, IL, USA) was used for data entry and statistical analysis. "SPSS software version 25 for Windows (SPSS, Inc.)" was used throughout the entire procedure. Following the removal of extreme values identified using box and whisker plots, the data were evaluated for normality using Shapiro-Wilk's test and for homogeneity of variance using Levene's test. Parametric tests were employed, and the demographic data

variables (age, GSV, and BMI) were normally distributed ($P>0.05$). Nonparametric tests were employed as the Villalta score variable since the other variables were not normally distributed ($P<0.05$). The mean and standard deviation of quantitative data, including age, GSV, BMI, and Villalta score factors, were displayed for descriptive statistics. The frequency and percentage were provided for the qualitative factors, including recurrence rate, post-operative complications, gender, CEAP categorisation, and Villalta questionnaire variables.

To evaluate the differences between the radiofrequency group and the EVLA group in demographic factors (apart from gender), an independent t-test was employed. The comparison of the radiofrequency group with the EVLA group for the Villalta score was done using the Mann-Whitney *U* test. Differences between the radiofrequency group and the EVLA group were examined using the chi-square test (χ^2 -test) for CEAP classification, gender, post-operative complications, recurrence rate, and Villalta questionnaire variables. The threshold for significance was fixed at $P<0.05$.

RESULTS

This study included 70 patients diagnosed with unilateral lower limbs VV who fulfilled our inclusion criteria, assigned randomly into 2 equal groups; Radiofrequency (RFA) group and EVLA group.

The average age of the cases in RFA group and EVLA group was 36.51 ± 7.25 and 37.63 ± 7.48 years, respectively. The age, gender distribution, GSV diameter and BMI of the patients in both groups did not show a statistically significant difference (P -value >0.05) (Table 1).

Table 1: General characteristics of the two study groups:

Items	Groups (Mean $\pm$ SD)		χ^2 -value	<i>P</i> -value
	RFA group (<i>n</i> = 35)	EVLA group (<i>n</i> = 35)		
Age (Year), mean $\pm$ SD	36.51 $\pm$ 7.25	37.63 $\pm$ 7.48	0.632	0.529
GSV diameter(mm), mean $\pm$ SD	8.73 $\pm$ 2.06	8.65 $\pm$ 2.38	0.166	0.868
BMI(kg/m ²), mean $\pm$ SD	24.60 $\pm$ 3.23	25.94 $\pm$ 2.83	1.845	0.069
Gender, <i>n</i> (%)	Males	15(42.90%)	0.059	0.808
	Females	20(57.10%)		
CEAP, <i>n</i> (%)	C2	20(57.10%)	0.00	1.000
	C3	15(42.90%)		

P: Probability; $P>0.05$: Non-significant.

Regarding post-operative complications, 25(71.40%) patients in the RFA group and 29(82.90%) patients in the EVLA group suffered mild pain. None of the patients in the EVLA group developed burn, DVT, infection, or hyperpigmentation, while in the RF group, only one patient developed burn, one patient developed DVT, two patients developed infection, and four patients had hyperpigmentation. However, these findings show no statistically significant difference between the two groups

except for hyperpigmentation which showed a significantly higher level in the RFA group ($P= 0.039$) (Table 2).

Assessment of success rates revealed that the study population of both groups had almost the same immediate success rate, 97% for the RFA group and 98% for EVLA group. Moreover, the delayed success rate showed the same results, with 96% in the RFA group and 97% in the EVLA group. At 1-week and 1-month follow-ups, no recurrence

Table 2: Comparison of post-operative complication between groups:

Variables	Categories	Groups		χ^2 -value	P-value
		RFA group (n= 35)	EVLA group (n= 35)		
Pain	Mild	25(71.40%)	29(82.90%)	1.296	0.255
	Moderate	10(28.60%)	6(17.10%)		
Burn	Free	34(97.10%)	35(100%)	1.014	0.314
	Developed	1(2.90%)	0(0.00%)		
DVT	Free	35(100%)	34(97.10%)	1.014	0.314
	Developed	0(0.00%)	1(2.90%)		
Hyperpigmentation	Free	31(88.60%)	35(100%)	4.242	0.039*
	Developed	4(11.40%)	0(0.00%)		
Infection	Free	33(94.30%)	35(100%)	2.059	0.151
	Developed	2(5.70%)	0(0.00%)		
One week	No recurrence	35(100%)	35(100%)	0.00	1.000
	Recurrence	0(0.00%)	0(0.00%)		
One month	No recurrence	35 (100%)	35(100%)	0.00	1.000
	Recurrence	0(0.00%)	0(0.00%)		
Six months	No recurrence	32(91.40%)	33(94.20%)	0.215	0.643
	Segmental patency of GSV	3(8.60%)	2(5.70%)		

Data were expressed as count (percentage); χ^2 value: Chi-square value; P: Probability; *: Significant ($P < 0.05$).

was detected among the cases of both groups (Figures 1-4). However, at six months, 3 cases showed recurrence of VV in the RFA group and 2 cases in the EVLA group without a statistically significant difference in recurrence rates following surgery (P -value > 0.05). Also, the segmental patency of GSV in the RFA group and EVLA group during follow-up at one month was developed in 3 and 2 patients, respectively, without a statistically significant difference (P -value > 0.05) (Table 2).



Fig. 1: Male patient presented with great saphenous veins (dilated and tortuous) varicosities.



Fig. 2: 4 weeks Post radiofrequency ablation of GSV varicosities.

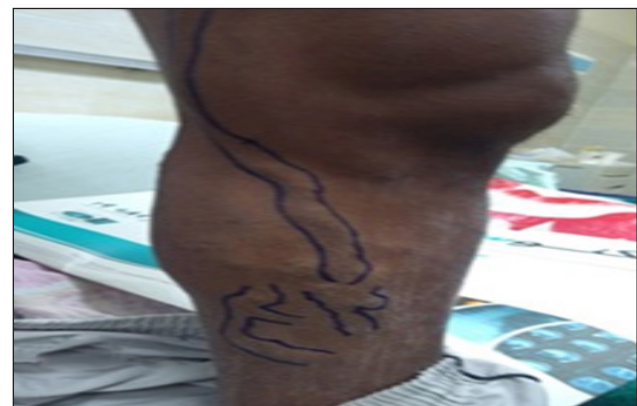


Fig. 3: Male patient presented with varicosities of GSV and its tributaries.



Fig. 4: 4 week Post LASER ablation of GSV varicosities.

The mean $\pm$ SD values of the overall Villalta score in the RFA group and EVLA group were 1.20 ± 0.41 and 1.31 ± 0.39 , respectively. The statistical analysis revealed no significant differences between the two groups ($P = 0.953$).

Analyzing the components of the short form 36 health survey questionnaire, the general health of the patients showed highly significant differences between pre-operative and post-operative general health distribution within RFA and EVLA groups ($P= 0.0001$ for both), denoting an improvement post-surgery in both groups. However, there were no significant differences in health in general between the RFA group and the EVLA group pre-operatively ($P= 0.771$) and post-operatively ($P= 0.535$) (Table 3).

The pre-operative and post-operative limitations of activity distribution within each group showed a highly significant reduction after surgery within both groups ($P= 0.0001$ for both groups). Conversely, a comparison between both groups for limitations of activities distributions showed non-significant differences in RFA and EVLA groups pre-operatively ($P= 0.334$) and post-operatively ($P= 1.000$) (Table 3).

The social activities of the patients were significantly enhanced post-operatively as 100% of the cases of both study groups categorized their social activities as not affected at all after surgery showing highly significant differences ($P= 0.0001$ for both groups) but with non-significant differences between RFA and EVLA groups pre-operatively ($P= 0.508$) and post-operatively ($P= 1.000$) (Table 3).

Regarding physical and emotional health problems, all participants of the two study groups were affected preoperatively by physical and emotional health problems. Post-operatively, only a few cases in both groups suffered such problems, as shown in Table (3). These results revealed significant differences between pre-operative and post-operative physical and emotional health problems distribution within RFA and EVLA groups ($P= 0.0001$ for both), but without a significant difference when comparing both groups (P -value >0.05).

The pre-operative and post-operative pain distributions showed that there were significant differences between pre-operative and post-operative pain distributions within RFA and EVLA groups ($P= 0.0001$ for both groups) and non-significant differences between RFA and EVLA groups at pre-operative ($P= 0.953$) and post-operative ($P= 1.000$) (Table 4).

DISCUSSION

Varicose veins are enlarged saphenous veins and/or their branches, or non-saphenous superficial leg veins measuring three millimeters or more in diameter. They are associated with valve function failure and wall changes, causing different pathological signs and symptoms^[13].

This condition affects up to 25-30% of the general population and is caused commonly by GSV reflux

and insufficiency^[14,2,15]. Duplex Ultrasound (DUS) can accurately diagnose VVs and reveal previously unknown facts about vein architecture and function^[16].

VV can be treated by endovenous surgeries such as RFA and, recently, EVLA^[4]. These techniques are favorably performed with local anesthetics with oral anxiolytics for patients who are apprehensive^[6].

There aren't many research comparing the two therapies in Egypt. Seventy patients with symptomatic VVs caused by inadequate SFJ and GSV (mean diameter of 9 mm) evaluated with Duplex Ultrasound were included in the current research. Two groups of volunteers were formed; the first group was treated with RFA, while the second group was treated with EVLA. The GSV diameter, BMI, and age of both groups were comparable.

Regarding patients, baseline characteristics, and demographics, the current study's patients had an average age of 37 years, about 60% were females, and the mean BMI was 25kg/m², respectively. Older age and higher BMI may support the association between these factors and VV prevalence identified in previous studies in Egypt^[17,18].

Additionally, earlier research indicated that the occurrence of VV is more common in females compared to males. This could be attributed to factors such as increased body mass index (BMI), greater number of childbirths, and the consumption of oral contraceptives, which can cause hormonal imbalances.

The success rate of the two procedures was comparable in the RFA and EVLA groups, 97% vs. 98% at early post-operatively, which decreased only 1 % in both groups at 6 months post-operatively. This finding is supported by multiple prior studies, which reported a success rate of occlusion of GSV in more than 90% of the cases at follow-ups varying between 1 month and 1 year after RFA and EVLA procedures^[20-22].

Moreover, El Kilic *et al.*, found that the occlusion success rate was comparable between RFA and EVLA early post-intervention but was higher in favor of RFA up to 5 years^[23].

It is worth noting that the current study showed higher rates than some of the previous ones, which may be explained by differences in the follow-up points and in the technique.

A Visual Analogue Scale (VAS) was used to quantify post-operative discomfort and self-satisfaction. Following the intervention, the current investigation revealed non-statistically significant changes between the groups ($P>0.05$).

Table 3: Distribution of pre-operative and post-operative general health, limitations of activities, distributions of social activities, physical and emotional health problems in both groups:

Distribution of general health			
Items	Category	RFA group (n= 35)	EVLA group (n= 35)
Pre-operative	Fair	3(8.60%)	4(11.40%)
	Good	8(22.90%)	7(20.00%)
	Very good	15(42.90%)	16(45.70%)
	Excellent	9(25.70%)	8(22.90%)
Post-operative	Fair	0(0.00%)	0(0.00%)
	Good	0(0.00%)	0(0.00%)
	Very good	0(0.00%)	0(0.00%)
	Excellent	35(100%)	35(100%)
Limitations of activities			
Pre-operative	Not limited at all	13(37.10%)	10(28.60%)
	Limited a little	21(60.00%)	21(60.00%)
	Limited a lot	1(2.90%)	4(11.40%)
Post-operative	Not limited at all	31(88.60%)	31(88.60%)
	Limited a little	4(11.40%)	4(11.40%)
	Limited a lot	0(0.00%)	0(0.00%)
Distribution of social activities			
Pre-operative	Slightly	25(71.40%)	24(68.60%)
	Moderately	3(8.60%)	6(17.10%)
	Not at all	7(20.00%)	5(14.30%)
Post-operative	Slightly	0(0.00%)	0(0.00%)
	Moderately	0(0.00%)	0(0.00%)
	Not at all	35(100%)	35(100%)
Distribution of physical health problems			
Items	Category	RFA group (n= 35)	EVLA group (n= 35)
Pre-operative	Free	0(0.00%)	0(0.00%)
	Developed	35(100%)	35(100%)
Post-operative	Free	30(85.70%)	28(80.00%)
	Developed	5(14.30%)	7(20.00%)
Distribution of emotional health problems			
Pre-operative	Free	0(0.00%)	0(0.00%)
	Developed	35(100%)	35(100%)
Post-operative	Free	30(85.70%)	30(85.70%)
	Developed	5(14.30%)	5(14.30%)

Data were presented as counts (percentages); P: Probability; *: Significant ($P < 0.05$).

Table 4: Pre-operative and post-operative distributions of pain and “how much pain interferes with normal work” in both groups:

Distribution of pain			
Items	Category	RFA group (n= 35)	EVLA group (n= 35)
Pre-operative	None	4 (11.40%)	3 (8.60%)
	Mild	23 (65.70%)	25 (71.40%)
	Very mild	5 (14.30%)	4 (11.40%)
	Moderate	3 (8.60%)	3 (8.60%)
Post-operative	None	28 (80.00%)	28 (80.00%)
	Mild	0 (0.00%)	0 (0.00%)
	Very mild	5 (14.30%)	5 (14.30%)
	Moderate	2 (5.70%)	2 (5.70%)
How much pain interferes with normal work			

Distribution of pain			
Items	Category	RFA group (n= 35)	EVLA group (n= 35)
Pre-operative	None	10 (28.60%)	13 (37.10%)
	Mild	0 (0.00%)	0 (0.00%)
	Very mild	25 (71.40%)	22 (62.90%)
	Moderate	0 (0.00%)	0 (0.00%)
Post-operative	None	31 (88.60%)	28 (80.00%)
	Mild	2 (5.70%)	3 (8.60%)
	Very mild	2 (5.70%)	4 (11.40%)
	Moderate	0 (0.00%)	0 (0.00%)

Data were presented as counts (percentages) *P*: probability * Significant ($P<0.05$)

On pain and other outcomes, some earlier research revealed inconsistent results on the reliability of RFA vs LA. The results of a prior research by Tofigh *et al.*, which found that post-operative discomfort was comparable following both RFA and EVLA, provide credence to this^[24].

However, prior studies have demonstrated that the LA group experienced much less post-intervention discomfort than the RFA group^[25]. According to Karathanos *et al.*, EVLA had better life quality and less discomfort than RFA in the early stages, but these differences persisted a year after surgery^[22].

Nonetheless, a number of earlier studies showed that patients treated with RFA experienced less ecchymosis, discomfort, and a greater quality of life, as well as less post-operative pain, particularly in the early post-operative phase, than those treated with EVLA^[26–28,23].

Another study that compared the effects of RFA and EVLA on post-operative pain and bruising showed that patients who underwent RFA had lower pain and bruise scores than patients who underwent EVLA. These differences were present only in the bilateral group rather than the unilateral group. However, the rate of success was similar in both groups^[29].

These differences between the current study and the previous studies regarding pain seem not clinically significant and may be partially attributed to the differences in the point of follow-up, the inclusion of bilateral and unilateral cases, and the sample size.

Regarding recurrence rate, the present study showed no recurrence rate in either group post-intervention except at 6 months, which was insignificantly lower in the EVLA group than in RFA (2 vs. 3%).

In agreement, a systematic review and meta-analysis showed that the recurrence rates after RFA and EVLA were similar up to 5 years after surgery^[30]. However, the previous study differed from the present one in that it showed a higher rate (36.6%) than the current study (about 2.5%). The difference may be due to the difference in the period of follow-up in both studies (6 months vs. 5 years).

In addition, Tofigh *et al.*, agreed with the current study's findings, as they found a similar recurrence rate in RFA and EVLA at 12 months post-intervention^[24].

As for post-operative complications other than pain, the current study found comparable complications post-intervention in the rates of burn, DVT, and infection, while the EVLA group had significantly lower hyperpigmentation than the RFA group post-operatively.

The present findings are in agreement with previous ones, which found that pain and ecchymosis are frequent after the EVLA procedure while skin burns, DVT, pulmonary embolism, and nerve injuries rarely occur^[31–33].

Additionally, previous research was found supportive of the current results having a similar complication rate regarding GSV reflux, DVT, bleeding, and phlebitis after both RFA and LA^[25,21–22].

Conversely, El Kilic *et al.*, discovered that EVLA was linked to noticeably higher incidence of complications than RFA^[23].

After surgery, both groups' health and life quality scores improved and were comparable. When the subscales of the short form 36 health survey questionnaire were examined separately, they revealed that there were no differences between the groups after surgery and that both groups had improved in terms of social activities, activity limitation, distribution of physical and emotional health issues, and general health when compared to a year prior to surgery.

Rasmussen *et al.*, 's findings that health and life quality had improved in the RFA and LA groups by the 1-year follow-up lend credence to this. This trial was different from the current one, though, because the RFA group had better physical functioning and less physical discomfort than the EVLA group^[25].

Furthermore, RFA-treated patients were able to return to work more quickly than EVLA-treated patients, according to some studies^[26,27,23,25].

Additionally, a research concurs that the total amount of time needed to return to work following RFA and EVLA was almost same; however, a greater proportion of the EVLA group returned to work on Day 1 (75% vs. 50%)^[21].

CONCLUSION

It is concluded that both RFA and LA are less invasive therapies with fewer complications. Both interventions improve pain and life quality similarly in patients with varicose veins.

Although the surgical stripping operation was the gold standard for years, the new NICE guidelines recently recommended endogenous ablation. This supports our results and recommendation to use either RFA or LA as a first choice in treating primary varicose veins.

RECOMMENDATIONS

The authors of this study recommend increasing the sample size, following the cases for a longer period (1 year or more), and considering unilateral vs. bilateral cases during future studies.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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