



Cross-sectional Study

Non-randomized comparative study of three methods for great saphenous vein ablation associated with mini-phlebectomy; 48 months clinical and sonographic outcome

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ABSTRACT

Background: Varicose veins are one of the earliest clinical features of superficial venous insufficiency (SVI) of the lower limbs that affects around 20–40% of the population with a lot of burden on patients' quality of life (QoL) and health systems if left untreated. They are defined as subcutaneous veins in the lower extremities which are dilated to ≥ 3 mm in diameter in the upright position and retrograde flow of >0.5 s in duration. (VVs) could occur in the great saphenous vein (GSV) or small saphenous vein (SSV) and/or in any of their tributaries.

Methods: A prospective non-randomized comparative study for three methods of treatment of varicose veins was conducted. All symptomatic varicose veins with Clinical, Etiological, Anatomical, Pathophysiological (CEAP) Clinical classes of 2 or greater and demonstrated venous reflux with a duration of 0.5 s or greater on duplex ultrasound imaging GSV larger than 10 mm in diameter by duplex ultrasound were included.

Results: A total of 150 patients with 183 legs in all three groups are treated. The mean age of the patients in all groups was comparable (37.32) years, and a total of 87% were women. Demographic and preoperative clinical features, presentations, and anatomic characteristics were comparable in all groups. Disfigurement was the main presenting complaint in all. All postoperative complications were significantly higher in the group of surgery over 48 months of follow up the degree of satisfaction measured by VCSS score was highest among the RFA group followed by the EVLA group.

Conclusion: The results of our study suggest that the long-term results of endovenous thermal ablation methods (EVLA, RFA) are superior to open surgery for the management of varicose veins, with the RFA group showing better results in terms of improvement in QoL based on VCSS compared to the EVLA group.

1. Introduction

Varicose veins (VVs) are one of the earliest clinical features of superficial venous insufficiency (SVI) of the lower limbs that affects around 20–40% of the population with a lot burden on patients' quality of life (QoL) and health systems if left untreated [1,2]. The great saphenous vein (GSV) is much more commonly affected and this can commence in any part of the vein and tends over time to propagate distally and proximally as well as between superficial and deep systems [3,4].

Varicose veins are defined as subcutaneous veins in the lower extremities which are dilated to ≥ 3 mm in diameter in the upright position

and retrograde flow of >0.5 s in duration [5,6]. VVs could occur in the great saphenous vein GSV or small saphenous vein (SSV) and/or in any of their tributaries [7].

Most current theories that explain the pathophysiology of the VVs are that they represent primary venous disease and occur as a result of the structural weakening of the wall of the vein, which can be focal in nature or diffuse [8]. Since VVs are considered a disease of the developed countries, hence a lot of advancement has been made in the modalities of their management [9].

While open surgery used to be the only definitive management of patients diagnosed with VVs, albeit with recurrence rates of around 40%, in the past two decades it has been broadly abandoned in most

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parts of the world and replaced with endovenous thermal, mechanical, or chemical ablations [10,11].

Recently, the percutaneous thermal ablation modalities attained worldwide acceptance. It includes endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) [12]. Each of these methods that causing thermal-induced energy causing transmural injury to the endothelium of the vein with eventual thrombosis and closure [13]. Both methods of ablation have undergone a lot of advancement to achieve optimal results and decrease recurrence rates with 2–5% recurrence rates reported [14,15].

The introduction of the endovenous thermal ablation modalities is relatively new in our country, with open surgery still being practiced in a lot of vascular centers. To the best of our knowledge, there hasn't been any published data comparing open surgery for VVs with short and long-term outcomes of both EVLA and RFA in Iraq.

2. Patients and methods

We conducted a prospective non-randomized comparative study for three methods of treatment of VVs. A total of one hundred and fifty patients were included between June 2016 and December 2019. Verbal and written consent was obtained from all participants for publication. All symptomatic VVs with Clinical, Etiological, Anatomical, Pathophysiological (CEAP) Clinical classes of 2 or greater and demonstrated venous reflux with a duration of 0.5 s or greater on duplex ultrasound imaging, all GSV larger than 10 mm in diameter by duplex ultrasound were consecutively included.

All patients who presented with secondary varicose veins were excluded from the study. The protocol and conduct of this study were reviewed and approved by our institutional review board. The same vascular surgeon performed all the clinical evaluations and endovenous thermal ablation procedures. The same sonographer interpreted the duplex findings. Reflux was considered significant if reversal of flow was present for 0.5 s or more after compression and decompression of the distal vein segment in the standing position. The diameters of the GSV were measured at several points, including the saphenofemoral junction (SFJ); the high, mid, and low thigh; and the high, mid, and low calf. Disease severity was assessed using the "C" of the CEAP clinical classification. Treatment modality chose according to the decision of the surgeon and the patient's preference.

All procedures were carried out under spinal anesthesia no tumescent anesthesia was used to minimize the bias of the outcomes. The group of surgery all has standard high ligation of the saphenofemoral junction with the stripping of the GSV down to 2 cm below knee joint added to that multiple mini-phlebectomies for all visible and palpable abnormal dilated veins. For the group EVLA, we used Surgical laser ENDOTHERME™ 1470 ring light radial fibers by Isomedical, France. While for the group of RFA we used ThermoBLOCK Thermal Coagulation RF device Turkey.

All the cases were day cases and the protocol of follow-up and treatment was used for all three groups. They were followed up for 48 months by clinical and Doppler evaluation. Our post-procedure follow-up protocol includes duplex ultrasound scanning within 1 week; then at 1, 6, and 12 months after ablation; and annually thereafter. The Venous Clinical Severity Score (VCSS) [16] was used to evaluate the outcome postoperatively for all the 3 groups.

Patient demographics collected included age, gender, and occupation comorbidities. Other covariates captured included the pretreatment baseline characteristics such as disease severity by CEAP classification scores and GSV diameter.

Treatment details recorded included the anatomic location of vein ablated and adjunctive procedures such as phlebectomy. Posttreatment complications recorded included pulmonary embolism, DVT, endothermal heat-induced thrombosis, and neuropathy.

Recurrence data recorded included the date, anatomic site, and pattern of recurrence. The lower extremities of patients who underwent

bilateral saphenous ablation were considered separately. The primary endpoints for the study were clinical recurrence and duplex-detected recurrence.

All statistical computation is enhanced by using the (IBM® SPSS®) Statistics 21. The data had been coded, tabulated, and presented in a descriptive form. The statistical procedure that was applied to determine the results of the present study included: Descriptive statistical data analysis (Frequency, Percentage, Mean, and Stander deviation). For the Inferential data analysis: The chi-Square test used. To calculate the differences between the survival curves, the log-rank test was used. A *p*-value of less than 0.05 was considered statistically significant. Kaplan-Meier survival analysis was used to assess time to clinical recurrence and the VCSS post-operative score was used to assess the degree of satisfaction from the procedure.

Ethical approval obtained from our Institutional Review Board by act no. 1178/September 8th 2021. Our work has been reported in line with the STROCSS2021 criteria [17]. This study was registered on [ResearchRegistry.com](https://www.researchregistry.com) (registration number: researchregistry7854).

3. Results

A total of 150 patients with 183 legs in all three groups were treated. The mean age of the patients in all groups was comparable (37.32) years, and a total of 87% were women. Demographic and preoperative clinical features, presentations, and anatomic characteristics were comparable in all groups. Strangely pain was not an important presentation for all groups, while disfigurement was the main presenting complaint in all. In this series of patients, the frequency of the right and left sides were statistically not significant. The occupation of the patients was again comparable in all groups, as the more frequent were housewives (73% of all the cases). The majority were not smokers. The body mass index (BMI) calculation showed that most of the patients were overweight (mean BMI = 24.47), the significant point is that the rate of overweight and obesity was significantly higher in the group of surgery (Table 1).

The preoperative CEAP class 4 was the most frequent of the three groups, while CEAP class 5 was the second most frequent. The preoperative VCSS score for all groups was nearly similar 20.9–21.3 (mean 21.55).

The preoperative Doppler measured reflux was grade three in the majority for all groups (EVLA grade 3 = 84%, RFA grade 3 = 80%, Surgery grade 3 = 68%). In all groups, mini-phlebotomy was performed for all and in only a minority accessory saphenous was ablated (Table 2). All postoperative complications (pain, hematoma, swelling, nerve damage, infection, Deep vein thrombosis (DVT), pulmonary embolism (PE), and Endovenous heat-induced thrombosis (EHIT) were significantly higher in the group of surgery as shown in Table 3. Over 48 months of follow up the degree of satisfaction measured by the VCSS score was highest among the RFA group followed by the EVLA group as demonstrated by the Kaplan-Meier graph in Fig. 1.

According to the study of the association between (EVLA, RF, and Surgery) cases concerning the sociodemographic characteristics, there were statistically significant associations (or differences) between EVLA, RF, and Surgery) cases in the site of the VV (*p*-value = 0.038) and General exam (*p*-value = 0.002) because the result of the *p*-value was less than the common alpha of 0.05. While, there were no statistically significant associations (or differences) between EVLA, RF, and Surgery) cases in other sociodemographic characteristics as the (*p*-value >0.05) (Table 4).

There was a statistically significant difference between EVLA, RF, and Surgery cases in Accessory saphenous vein ablation (*p*-value = 0.000) because the result of the *p*-value was less than 0.05. (Table 5).

Over the entire duration of the study, the sonographic rate of recurrence was higher in the group of surgery and lowest in the group of RFA. While cosmetic complaints were again higher in surgery cases and lowest in RFA cases (Table 6).

Table (1)
Distribution of the preoperative demographics.

Demographics	Items	EVLA cases		RFA Case		Surgery case		All	
		N	%	N	%	N	%	N	%
Age	<25	3	6.0	6	12	5	10	14	9.33
	25–34	19	38.0	15	30	16	32	50	33.33
	35–44	17	34.0	17	34	21	42	55	36.67
	45–54	9	18.0	10	20	6	12	25	16.67
	>54	2	4.0	2	4	2	4	6	4.00
	Mean ± S.D	37.16 ± 8.51		38.24 ± 9.99		36.56 ± 8.74		37.32 ± 9.07	
Sex	Male	21	42.0	23	46	19	38	63	42.00
	Female	29	58.0	27	54	31	62	87	58.00
Site	Right	15	30.0	21	42	24	48	60	40.00
	Left	19	38.0	16	32	22	44	57	38.00
	Bilateral	16	32.0	13	26	4	8	33	22.00
Pain	No	50	100.0	48	96	50	100	148	98.67
	Yes	0	0.0	2	4	0	0	2	1.33
Disfigurement	No	0	0.0	2	4	0	0	2	1.33
	Yes	50	100.0	48	96	50	100	148	98.67
Job	Employ	7	14.0	8	16	12	24	27	18.00
	Free lance	1	2.0	8	16	3	6	12	8.00
	Housewife	27	54.0	21	42	25	50	73	48.67
	Barber	8	16.0	7	14	3	6	18	12.00
	Restaurant	7	14.0	6	12	7	14	20	13.33
Smoking	No	41	82.0	43	86	39	78	123	82.00
	Yes	9	18.0	7	14	11	22	27	18.00
Comorbidities	No	44	88.0	49	98	42	84	135	90.00
	Yes	6	12.0	1	2	8	16	15	10.00
	Obese	3	50.0	0	0	5	62.5	8	53.33
If Yes	HTN	3	50.0	1	100	1	12.5	5	33.33
	type 2DM	0	0.0	0	0	2	25	2	13.34
	Total	6	100.0	1	100	8	100	15	10.00
BMI	Underweight	0	0.0	0	0	2	4	2	1.33
	Normal weight	21	42.0	23	46	26	52	70	46.67
	Over Weight	27	54.0	26	52	18	36	71	47.33
	Obese	2	4.0	1	2	4	8	7	4.67
	Mean ± S.D	24.86 ± 3.07		24.14 ± 2.99		24.42 ± 3.86		24.47 ± 3.32	
General exam	1	38	76.0	46	92	49	98	133	88.67
	2	12	24.0	4	8	1	2	17	11.33
Total		50	50	100.0	50	100	50	100	150

Table (2)
Distribution of the preoperative workup and operative details.

Parameters	Items	EVLA cases		RFA Case		Surgery case		All	
		N	%	N	%	N	%	N	%
CEAP	1	1	2	0	0	0	0	1	0.67
	3	3	6	4	8	2	4	9	6.00
	4	29	58	32	64	23	46	84	56.00
	5	17	34	14	28	22	44	53	35.33
	6	0	0	0	0	3	6	3	2.00
	Mean ± S.D	4.22 ± 0.74		4.2 ± 0.57		4.53 ± 0.68		4.31 ± 0.68	
VCSS	<15	4	8	1	2	6	12	11	7.33
	15–20	16	32	13	26	15	30	44	29.33
	>20	30	60	36	72	29	58	95	63.33
		Mean ± S.D	21.32 ± 5.3		22.44 ± 3.68		20.9 ± 4.86		21.55 ± 4.68
Doppler reflux grade	1	0	0	0	0	3	6	3	2.00
	2	8	16	10	20	13	26	31	20.67
	3	42	84	40	80	34	68	116	77.33
Phlebectomy	2	49	98	50	100	50	100	149	99.33
	4	1	2	0	0	0	0	1	0.67
Accessory saphenous vein ablation	No	18	36	22	44	50	100	90	60.00
	Yes	32	64	28	56	0	0	60	40.00
Hospital stay	1	50	100	50	100	50	100	150	100.00
Total		50	100	50	100	50	100	150	100

4. Discussion

This non-randomized comparative study between endovenous thermal ablation methods (EVLA and RFA) and open surgery for managing varicose veins demonstrates the endovenous methods to be more superior to open surgery over the course of 48 months of follow-up in terms of improvement in QoL based on VCSS.

While other studies have shown both modalities of RFA and EVLA to be as equally effective over the short term and more than one-year follow-up [18–21], we believe that the decline of the VCSS in our study is due to the fact that we performed the endovenous procedures in the theatre under spinal anesthesia making with the patients very comfortable with the whole experience.

As the pain has not been the major complaint of the patients,

Table (3)
Distribution of the postoperative complications.

Parameters	Items	EVLA cases		RF Cases		Surgery cases		All	
		N	%	N	%	N	%	N	%
pain VAS	1	0	0	0	0	1	2	1	0.67
	2	1	2	1	2	0	0	2	1.33
	3	7	14	2	4	3	6	12	8.00
	4	15	30	9	18	4	8	28	18.67
	5	11	22	13	26	3	6	27	18.00
	6	9	18	13	26	10	20	32	21.33
	7	4	8	5	10	11	22	20	13.33
	8	1	2	7	14	12	24	20	13.33
	9	2	4	0	0	4	8	6	4.00
	10	0	0	0	0	2	4	2	1.33
		Mean ± S.D	4.92 ± 1.54		5.56 ± 1.47		6.6 ± 1.91		5.69 ± 1.79
Hematoma	No	47	94	48	96	38	76	133	88.67
	Yes	3	6	2	4	12	24	17	11.33
Swelling	No	48	96	47	94	46	92	141	94.00
	Yes	2	4	3	6	4	8	9	6.00
Nerve damage	No	49	98	49	98	47	94	145	96.67
	Yes	1	2	1	2	3	6	5	3.33
Infection	No	49	98	48	96	45	90	142	94.67
	Yes	1	2	2	4	5	10	8	5.33
DVT	No	49	98	49	98	49	98	147	98.00
	Yes	1	2	1	2	1	2	3	2.00
PE	No	50	100	50	100	50	100	150	100.00
EHIT	Yes	50	100	49	98	50	100	149	99.33
	Yes	0	0	1	2	0	0	1	0.67
Vein removed completely	No	0	0	0	0	0	0	0	0.00
	Yes	50	100	50	100	50	100	150	100.00
Neo arch formation	No	50	100	50	100	50	100	150	100.00
	Yes	0	0	0	0	0	0	0	0.00
Total		50	100	100	50	100	50	100	150

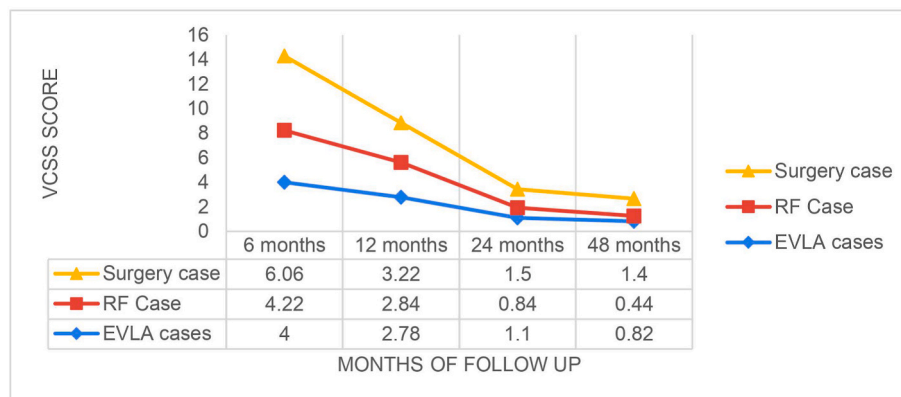


Fig. 1. 48 months of follow-up the degree of satisfaction measured by the VCSS score among the RFA group followed by the EVLA group is demonstrated by the Kaplan-Meier graph.

therefore, they have been highly contempt with the immediate cosmetic results provided by the intraoperative phlebectomies done in the same session. While other studies have shown the superiority of EVLA over RFA after 6 months of follow-up [22,23].

Although most of these studies don't have the same follow-up period of 48 months as ours and have reported a shorter duration of follow-up, the number of the study population is close to ours with minor changes as economic problems in our locality make performing minimally invasive procedures by our teams more challenging.

Our results have shown statistically significant improvement in QoL in the RFA group over the EVLA group and both of them over surgery after 48 months of follow-up, even though the majority of the patients in all groups have undergone micro-phlebectomy in the same session due to patient preference of removing the dilated, tortoise veins surgically over other methods yet patient satisfaction regarding cosmetic results have been equally superior to the open surgery group.

Strengths: The results of this study that superiority in short term and long-term for RFA is different from most all other studies, which in general in favor EVLA [3,4,12]. As well the duration of clinical and sonographic follow-up is relatively longer than most of the researchers about VVs.

Limitations: The sample size of our groups of patients is relatively small.

5. Conclusion

The results of our study suggest that the long-term results of endovenous thermal ablation methods (EVLA, RFA) are superior to open surgery for the management of varicose veins, with the RFA group showing better results in terms of improvement in QoL based on VCSS compared to the EVLA group. We recommend further groups take this finding into consideration and start further investigations.

Table (4)
Association between (EVLA, RF and surgery) and Demographics.

Demographics	Items	EVLA cases		RF Case		surgery case		Significant Test	
		N	%	N	%	N	%	χ^2	p-value
Age	<25	3	6.0	6	12	5	10	3.142	0.925
	25-34	19	38.0	15	30	16	32		
	35-44	17	34.0	17	34	21	42		
	45-54	9	18.0	10	20	6	12		
	>54	2	4.0	2	4	2	4		
	Mean \pm S.D	37.16 \pm 8.51		38.24 \pm 9.99		36.56 \pm 8.74		F = 0.437(0.647)	
Sex	Male	21	42.0	23	46	19	38		
	Female	29	58.0	27	54	31	62		
Site	Right	15	30.0	21	42	24	48	10.138	0.038
	Left	19	38.0	16	32	22	44		
	Bilateral	16	32.0	13	26	4	8		
Pain	No	50	100.0	48	96	50	100	4.053	0.132
	Yes	0	0.0	2	4	0	0		
Disfigurement	No	0	0.0	2	4	0	0	4.054	0.132
	Yes	50	100.0	48	96	50	100		
Job	Employ	7	14.0	8	16	12	24	11.256	0.188
	Free lance	1	2.0	8	16	3	6		
	Housewife	27	54.0	21	42	25	50		
	Barber	8	16.0	7	14	3	6		
	Restaurant	7	14.0	6	12	7	14		
Smoking	No	41	82.0	43	86	39	78	1.084	0.582
	Yes	9	18.0	7	14	11	22		
Comorbidities	No	44	88.0	49	98	42	84	5.778	0.056
	Yes	6	12.0	1	2	8	16		
	Obese	3	50.0	0	0	5	62.5		
If Yes	HTN	3	50.0	1	100	1	12.5		
	type 2DM	0	0.0	0	0	2	25	8	100
	Total	6	100.0	1	100	8	100		
BMI	Underweight	0	0.0	0	0	2	4	8.599	0.197
	Normal weight	21	42.0	23	46	26	52		
	Over Weight	27	54.0	26	52	18	36		
	Obese	2	4.0	1	2	4	8		
	Mean \pm S.D	24.86 \pm 3.07		24.14 \pm 2.99		24.42 \pm 3.86			
General exam	1	38	76.0	46	92	49	98	12.87	0.002
	2	12	24.0	4	8	1	2		

Table (5)
Comparison of the (EVLA, RFA and Surgery) parameters.

Parameters	Items	EVLA cases		RF Case		surgery case		Significant Test	
		N	%	N	%	N	%	χ^2	p-value
CEAP	1	1	2	0	0	0	0	12.016	0.151
	3	3	6	4	8	2	4		
	4	29	58	32	64	23	46		
	5	17	34	14	28	22	44		
	6	0	0	0	0	3	6		
	Mean \pm S.D	4.22 \pm 0.74		4.2 \pm 0.57		4.53 \pm 0.68		F = 3.63(0.029)	
VCSS	<15	4	8	1	2	6	12		
	15-20	16	32	13	26	15	30		
	>20	30	60	36	72	29	58		
	Mean \pm S.D	21.32 \pm 5.3		22.44 \pm 3.68		20.9 \pm 4.86		F = 1.456(0.237)	
Doppler reflux grade	1	0	0	0	0	3	6		
	2	8	16	10	20	13	26		
	3	42	84	40	80	34	68		
Phlebectomy	2	49	98	50	100	50	100	2.013	0.365
	4	1	2	0	0	0	0		
Accessory saphenous vein ablation	No	18	36	22	44	50	100	50.667	0.000
	Yes	32	64	28	56	0	0		

Table (6)
Comparison of the rate of recurrence of the VVs and cosmetic outcome for the 3 groups.

parameters	Items	EVLA cases		RF Case		Surgery case		Significant Test	
		N	%	N	%	N	%	χ^2	p-value
Varicose Vein recurrence by annual Doppler	No	47	94	48	96	47	94	0.264	0.876
	Yes	3	6	2	4	3	6		
Cosmetic complain	Yes	48	96	47	94	34	68	20.266	0.000
	No	2	4	3	6	16	32		

Ethical approval

Ethical approval obtained from our Institutional Review Board by act no. 1178/September 8th, 2021.

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Author contributions

AB; data collection, performing surgeries, study design, statistical analysis, draft revising, corresponding author and grantor.

DFS: data collection, performing surgeries, study design, statistical analysis, draft revising.

BHS: study design, statistical analysis, draft revising.

Declaration of competing interest

No conflicts of interest to declare.

Registration of research studies

1. Name of the registry: [ResearchRegistry.com](https://www.researchregistry.com)
2. Unique Identifying number or registration ID: researchregistry7854
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): <https://www.researchregistry.com/browse-the-registry/#home/registrationdetails/626beafb21bfba001e109c34/>

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Consent

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request".

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Abbreviations

Not applicable.

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