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Comparison of Endovenous Laser versus Radiofrequency Ablation in the Treatment of Primary Long Saphenous Varicose Veins

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Abstract

Background: **Endovenous laser ablation (EVLA)and radiofrequency ablation(RFA)are both associated with excellent technical, clinical, and patient-reported outcomes for the treatment of varicose veins.** ***Aim*****: to compare endovenous laser ablation and radiofrequency ablation in the treatment of primary long saphenous varicose veins.** ***Patients and Method*****: 40 patients scheduled for treatment of varicose veins were included and were divided randomly into 2 equal groups. Endovenous laser ablation was used for the first group and compared to a second group treated with Radiofrequency ablation. The success rate and postoperative results of both groups were compared to each other.** ***Results:*** **closure rate in EVLA group was 100% and in RFA group was 80%, radiofrequency ablation, and EVLA complications: skin burn 5% and 0 %, hyperpigmentation 10% and 0 %, and groin hematoma 0% and 5% respectively.** ***Conclusion*****: EVLA procedure seems to be superior to RFA in the treatment of long saphenous varicose veins.**

Keywords: Varicose veins; Endovascular laser ablation; Radiofrequency ablation

Introduction

Primary varicose vein disease is a widely prevalent condition. It is a sign of chronic venous disease, affecting around 25-40 percent of the adult population worldwide[1]. People are more likely to develop varicose veins as they get old, as wear and tear on the veins cause their walls to weaken, allowing the veins to enlarge[2]. The substantial cost of treating late complications such as chronic ulcers contributes to a high burden on healthcare resources[3]. The aim of treatment is not only to reduce symptoms but also to prevent long-term complications of chronic venous insufficiency[4]. Supporters of thigh saphenectomy thought that there will be fewer recurrences and improved hemodynamic and cosmetic results if thigh saphenectomy is added to high ligation and phlebectomy, During the past decade, there has been a renewed interest in minimally-invasive treatment and cost-effective as possible, consistent with extended relief and an acceptable cosmetic result[5]. Ultrasound guided procedures including endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were proved to have good clinical results and better patient satisfaction with high success rate[6]. These procedures were designed to ablate the great saphenous vein through a percutaneous approach to

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minimize the discomfort and complications associated with conventional stripping[7]. The RFA catheter delivers radiofrequency energy to achieve heat-induced venous spasm and collagen shrinkage whereas EVLA release thermal energy both to the blood and to the venous wall causing localized tissue damage. Relative simplicity and high patient satisfaction have made these procedures increasingly popular[8].

Patients and Methods

Forty patients were admitted to Suez Canal University Hospital, Ismailia-Egypt, in the period between September 2021 to March 2022 for ablation of the long saphenous vein, they were randomly divided into two equal groups EVLA and RFA. After approval of the study by the local ethical committee, patients who had venous disease categorized as C2-6 Ep As Pr according to CEAP classification with Saphe-no-Femoral junction incompetence with reflux more than 1 second indicated for varicose vein surgery. Pregnant females, deep venous thrombosis, secondary VV, recurrent VV, and short saphenous vein reflux patients were excluded from the study. All procedures were performed by the same surgical team.

Anesthesia

local tumescent anesthesia (lignocaine [20 ml 2% lignocaine with 1:100,000 adrenaline and 20mEq of sodium bicarbonate mixed with 480ml normal saline]) will be administered along the target vein under ultrasound guidance with sedation[9].

Technique of Radiofrequency ablation

Procedure

The patient was placed in the recumbent reverse Trendelenburg position. The limb is optimally positioned (hip abducted to approximately 30° and knee in gentle flexion). Access to the target vein will be achieved, by ultrasound-guided puncture of the GSV at the level of the knee using a micropuncture needle. Using a flexible guidewire, a 7F sheath was inserted, and Venefit (ClosureFAST™) catheter was advanced into the GSV through the sheath, the device used was closure RFG radiofrequency generator made in Ireland. The tip of the catheter was positioned 2.0 to 2.5 cm distal to the SFJ, and duplex ultrasound was used to confirm the position of the tip of the catheter after injection of Tumescent anesthesia. The heating element was activated with radiofrequency energy to 120 c for 20 seconds. The energy was delivered by withdrawing the catheter at an interval of 6.5 cm[10]

Technique of EVLA

Procedure

The patient was placed in the recumbent reverse Trendelenburg position. The limb is optimally positioned (hip abducted to approximately 30° and knee in gentle flexion). The target access site is at or slightly below the knee. A micro-access set (21-gauge needle and 6F sheath) is used to initiate access. The ring laser catheter is introduced, and its position was confirmed with ultrasound to be 2 cm below SFJ after Tumescent anesthesia was injected. The device used was endotherm 1470, made in France by ISO company. continuous mode and withdrawal of the catheter is performed; aiming for a target energy delivery of 60-80 Joules per centimeter (Jcm-1) till exit from the skin surface, assessment of the vein closure by gentle reentry of the catheter to the ablated part and test if it was entered or not.

Postoperative Care and Follow-Up Examination

The patient of each group was allowed to be discharged on the same day with instructions to keep the compression with

an elastic stocking for 2 weeks (day and night in the first week and day only in the second week). Follow-up was done at 1,3,6 month postoperatively clinically to assess any residual symptoms and radiological by duplex to assess closure rate which means complete occlusion of the vein without any patent segment, failure which means the presence of patent segment more than 5 cm with reflux and recurrence which means recanalization of the vein 6th months post-operative.

Results

Forty patients were included in the study, 17 patients (42.5%) were males, and 23 patients (57.5%) were females, they were randomly divided into two equal groups, 20 patients underwent RFA and the other 20 patients underwent EVLA with mean age 32.55± 4.181 years. According to CEAP classification[11] at presentation, clinically 15 patients (37.5%) were C2 VV, 19 patients (47.5%) were C3 VV, 4 patients (10%) were C4, and 2 patients (5%) were C6 . all of them (100%) presented with primary long saphenous VV as a result of refluxing long saphenous classified as (Ep, As & Pr), as shown in Table 1. Regarding pre-operative duplex, all patients (100%) had patent competent deep venous system, with dilated incompetent sapheno-femoral junction (SFJ) and great saphenous vein (GSV), the sapheno-popliteal junction (SPJ) and short saphenous vein (SSV) of all participants (100%) were competent with a diameter within normal range.

Table 1: CEAP classification of the studied population

	Frequency	Percent
C1	0	0%
C2	15	37.5%
C3	19	47.5%
C4	4	10%
C5	0	0%
C6	2	5%

The sapheno-femoral junction mean diameter was 9±3 mm with a minimum diameter of 5 mm and a maximum diameter of 16 mm, and the mean reflux time of the SFJ equals 3±1 sec. with minimum reflux of 0.7 sec. and maximum reflux of 5 sec..

While the great saphenous vein mean diameter was 8 ±3 mm with a minimum of 5mm and a maximum of 18 mm, the mean reflux time of the GSV equals 3±1 sec. with minimum reflux of 1 sec. and maximum reflux of 4 sec. (Table 2).

Table 2: pre-operative duplex US assessment

	Minimum	Maximum	Mean	Std. Deviation
Pre-operative SFJ diameter	5.0	16.0	9	3
Pre-operative SFJ reflux time	0.7	5	3	1
Pre-operative GSV diameter	5	18.0	8	3
Pre-operative GSV reflux time	1.0	3.0	3	1

Regarding the time of operation, it ranged between 20 and 45 minutes with a mean of 30± 5 minutes. All participants (100%) had early ambulation within a few hours

post-operative, all of them were allowed to be discharged on the same day of operation, and no associated post-operative functional disabilities were noted. All patients kept the elastic stocking for 2 weeks post-operatively the first week (day and night) second week (day only). On 6 month follow-up, patency of the ablated vein was assessed by using duplex ultrasound. All the 20 EVLA patients (100%) had completely occluded great saphenous vein with no patent intermittent segment, while in the other 20 RFA patients 16 patients (80%) had completely occluded great saphenous vein with no patent intermittent segment, and only 4 patients (20%) had an intermittent patent segment with an average length of ≤5 cm showing no residual refluxing. p-value was 0.053 which means that there was a significant difference. According to the pain score[12], the pain was relieved one week postoperatively for all patients who had pain in their symptoms preoperatively, there was no significant difference between the two groups regarding postoperative pain, Table 3.

Table 3: Descriptive statistics of Pre-op& Post-op pain

	EVLA				RFA			
	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.
Pre. op pain score	5	1	4	7	5	2	2	7
Post. op pain score	0	0	0	0	0	0	0	0

Regarding postoperative complications; In RFA group, one patient (5%) had skin burn at the site of cannulation and sheath insertion, Only 2 patients (10%) experienced post-ablation hyperpigmentation of the distal part of the great saphenous vein, and none of them had groin hematoma, While in EVLA patients, 1 patient (5%) had groin hematoma at the site of tumescent injection around the SFJ that was relieved soon after applying warm fomentations and application of recombinant hirudin gel, none of them had skin burn or hyperpigmentation, as shown in figure 1. In both groups, no patients showed symptoms of nerve injury, no patients had postoperative thrombophlebitis of the ablated vein or any of its tributaries. no reported cases of endovenous heat-induced thrombosis (EHIT).

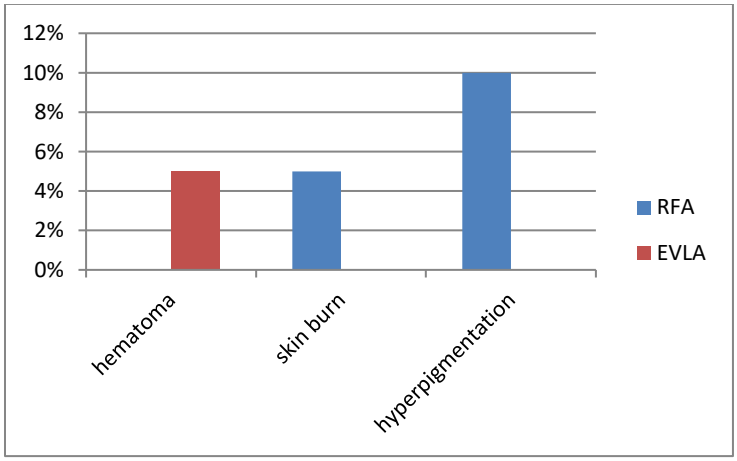

Figure 1: Bar graph showing postoperative adverse events

Discussion

Chronic venous insufficiency (CVI) and lower extremity varices that develop in association with this are important clinical condition that significantly affects the quality of life and have socioeconomic consequences. Significant progress has been made in the treatment of varicose veins in the last 10 years[13]. Endovenous ablation techniques have to a large extent replaced surgery. Thermal endovenous procedures such as RFA and EVLA have become the most used techniques. Several studies have compared these two different forms of ablation[14].

Figure 2: Post-operative Skin burn after RFA

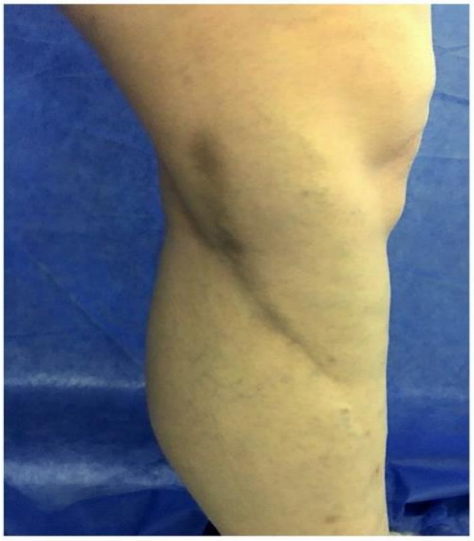

Figure 3: Post-operative hyperpigmentation after RFA

In our study, we found that the occlusion rate in RFA was 80% and in EVLA was 100% over 6 months of follow-up for the patients which agreed with Bozolgan et al (2017) in the EVLA results but disagreed with it in RFA results which were 93.2%[15]. However. Van den Bos et al evaluate 119 studies and recognize that success rates (which means total vein occlusion without patent segment) were 94% for EVLA and 84% for RF on the basis of results for 12320 legs which is different from our results and that mostly due to the difference in sample size[16]. In our study, No procedure-related major complication (DVT, pulmonary embolism) developed in both groups except One patient developed a second-degree burn after RFA procedure which agreed with the study conducted by Wozniak et al[17] in which there were no major complications occurred in both groups and only one patient had skin burn in RFA. From our point of view after finishing our study we assume that the most important differences between both techniques were the occlusion rate and complication rate as EVLA has a high occlusion rate and less complication rate. There was also a technical difference between both of them which make EVLA seems to be superior to RFA from our point of view, during EVLA we can gently re-enter the catheter in the ablated segments to test their closure which was not available in RFA.

Conclusion

After comparing both techniques through six months of follow-up, EVLA seems to be superior to RFA in the treatment of long saphenous varicose veins with less

complication and more patient satisfaction.

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