



A COMPARISON OF ENDOVENOUS LASER THERAPY (EVLT) AND RADIOFREQUENCY ABLATION (RFA) FOR THE TREATMENT OF VARICOSE VEINS

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ABSTRACT **Introduction:** Varicose vein is a common medical condition present in at least 10% of general population. The findings of varicose veins include dilated and tortuous veins, telangiectasias and fine reticular varicosities. There are a large number of complications like longer recovery time and higher recurrence rates with the conventional surgical stripping technique. EVLT and RFA are the novel minimally invasive treatment modalities with the advantages of safety, effectiveness and simplicity and leaves no scars. Its indication can be extended by combining surgical strategies with improved quality of life. **Aims and Objectives:** To compare EVLT and various effective minimal access methods (RFA) in the treatment of varicose veins and to evaluate cost effectiveness of these techniques. **Material and Methods:** This study of 80 patients of varicose veins treated using laser (EVLT) and Radio frequency generator unit (RFA) with bipolar applicator, Doppler and ultrasound machine to map the vein to be treated during procedure, was carried out between January 2019 to September 2020. Imaging was primarily done using duplex ultrasound as it is easily available, sensitive, non-invasive and relatively cost effective. **Results:** The study compared EVLT and RFA in terms of time taken for procedure, cost of procedure, response to therapy, complications, recurrence and need for re-intervention, and suggested that EVLT is significant at $p < 0.05$ that suggest significance of EVLT over RFA. In our study the recurrence rate was with EVLT (5.00%) and with RFA (22.5%), Hospital stay was less with EVLT (mean-1days) followed by RFA (mean-1.3days). Cost-effectiveness of different treatment modalities in our study calculated by cost ratio, the Cost Ratio in EVLT and RFA found 1:1.13 suggesting cost effectiveness of EVLT over RFA. **Conclusions:** . In terms of reduced postoperative pain, shorter sick leave, a faster resumption of the normal activities, and, in particular, the total absence of DVT, we can conclude that EVL is a good solution for all patients with anatomic and hemodynamic patterns for saphenous vein surgery. Treating full length of GSV is associated with less residual symptoms. Also small basic modifications in instrumentation can make big differences in the cost of the therapy. EVLT have more success rate in comparison to RFA. And more efficient mode of treatment because of higher elimination of junctional reflux, higher occlusion & ulcer healing rate.

KEYWORDS : Varicose veins; RFA: Radiofrequency Ablation; EVLT: Endovenous Laser Ablation.

INTRODUCTION

Varicose veins are the most common peripheral vascular diseases. The recognition of this entity and its treatment dates back to 500 BC when, **Hippocrates** attempted multiple venipunctures as a method for production of thrombosis. The modern concept of reverse flow and incompetency of the valves originated with **Brodie** (1846). Further contributions over the years have increased our knowledge of pathophysiology of varicose veins¹ although complete agreements on this and treatment remains yet to be realized. Varicose veins may be found in almost every part of body (**Nichoftson 1923**). The frequency of their appearance in the legs may make us forget this fact. The incidence of varices and their complications is not only an individual but also a national problem of great importance. The incidence of varicose veins ranges from 5-15% in males and 3-29% in females. Many men hours are lost in industry owing to the complications of varicose veins. As an example we are told by **Curwen and Scott** (1952) that in the United States of America 5900000 days were lost in the course of 1 year. Evidence of this nature should make us realize the effect of this disease on the economy of the nations. Varicose veins are present in atleast 10% of general population. The findings of varicose veins may include dilated and tortuous veins telangiectasias and fine reticular varicosities.

Risk factors for varicose veins include obesity, female sex, inactivity and family history. Varicose veins can be classified as primary or secondary. Primary varicose veins result from intrinsic abnormalities of the venous wall while secondary varicose veins are associated with deep or superficial venous insufficiency.

Chronic venous disorders (CVDs) of the lower extremity are commonly associated with venous hypertension, which is the result of reflux in one or more of the saphenous veins and their primary tributaries. For the treatment of these conditions with saphenous vein

incompetence there are a number of options like conservative management or elimination of these incompetent pathways using endovenous techniques or surgery.

Aims and Objectives:

This study was carried out to compare EVLT and RFA in the treatment of varicose veins, and to evaluate the cost effectiveness of these two techniques.

Material and Methods:

The study was conducted in a tertiary care centre, from January 2019 to October 2020, on patients of varicose veins who were admitted to wards/ presented to the outpatient setting. A total of 80 patients were taken and divided into 2 groups: (EVLT=40, RFA=40).

Settings and Design:

Patients were treated with *Biolitec Laser Machine (EVLT)* and *Celon Lab Power Radiofrequency generator unit (RFA) with Bipolar applicator*; Doppler and ultrasound machine with linear array 7.5-10 MHz transducer to map the vein to be treated during procedure. Imaging was done using duplex ultrasound. Post operative follow up was done at 1 month, 6 months, 12 months. Improvement on the CEAP grading was documented, follow up color Doppler was done and reflux at SFJ or SPJ, and occlusion of the ablated vein were recorded. Cost effectiveness was calculated for both the procedures.

OBSERVATION:

Table 1: Demographic and clinical data, and complications of both techniques:

S.No	Demographic and Clinical Data	EVLT (n=40)	RFA (n=40)
1.	Total limbs	40	40

2.	Age group (Median)	41-50	41-50
3.	Gender	M-81.25% F-18.75%	M-86% F- 14%
4.	Clinical presentation	C2-4 C5-6	38(96%) 36(90%) 2(5%) 4(10%)
Complications			
5.	Hyperpigmentation	2(5%)	8(20%)
6.	Parasthesia	1(2%)	5(12.5%)
7.	DVT	0(0%)	0(0%)
8.	Ecchymosis	9(22%)	18(45)
9.	Induration/hyperemia	7(17.5)	14(35%)
10.	Post-op Infection	1(2.50%)	4(10%)
11.	Edema	4(10%)	11(27.5%)
12.	Pulmonary Embolism	0(0%)	0(0%)
13.	Clinical Recurrence	6m 1y	3(7.5%) 6(15%)
14.	Neovascularisation	1(2%)	3(7.5%)

Table 2: Follow up ultrasound and Doppler evaluation:

Follow up	No of limbs with complete occlusion of treated veins				p-value
	EVLTV	%	RFA	%	
6 Months	33/36	91.66%	25/34	91.17%	.044
1 yr	31/32	96.87%	24/30	93.33%	.036
Follow up	No of limbs with elimination of SFJ/SPJ reflux				p-value
	EVLTV	%	RFA	%	
6 Month	35/36	97.22%	28/34	94.11%	.038
1 yr	31/32	96.87%	23/30	76.66%	.018

EVLTV shows reflux elimination in 96.87% case and RFA in 76.66% cases. Occlusion rate was significantly increased within 1 yrs in EVLTV group (96.87) while in RFA there is no significant improvement noted. In comparison to RFA, EVLTV shows significant improvement in occlusion rate (96.87%) . **Merchant RF, Pichot O et al** in their study found that vein occlusion rates were 96.8%, 89.2%, 87.1% and reflux free rates were 96.6%,87.3% & 88.2% at 1 week, 6 months & 12 month follows up.

Table 3: Response to therapy:

PROCEDURE	RESPONSE		TOTAL	X ² = 5.165 P=0.01153 P<0.05 Significant
	YES	NO		
EVLTV(n=40)	38	02	40	
RFA(n=40)	31	09	40	
TOTAL	69	11	80	

Table 4: Recurrence rates:

TYPE	VALUE	LOWER LIMIT	UPPER LIMIT
Risk exposed	95%	82.61%	99.5%
Risk unexposed	77.5%	62.29%	87.89%
Overall risk	86.25%	76.86%	92.32%
Risk ratio	1.226	1.022	1.47
Risk deffrence	17.5%	2.904%	32.10%
Etiologic fraction in population (EFP)	10.14%	0.9452%	19.34%
Etiologic fraction in exposed (EFE)	18.42%	2.188%	31.96%
ODD Ratio (OR)	5.409	1.1184	39.01
EFP/OR	45.09%	24.12%	66.06%
EFE/OR	81.87%	9.864%	96.35%

Procedure	Total Recurrent Cases(no.)	Recurrence Rate(%)	Total Successful Cases (no.)	Procedure Effectiveness (%)
EVLTV(n=40)	2	5%	38	95%
RFA (n=40)	9	22.5%	31	77.5%

In the study group we have observed the clinical recurrence rate (EVLTV 5% vs RFA 22.5%), but more duplex scanning recurrence (RFA 23.33%) at 1 yrs follow up. Due to a total or partial major recanalization of saphenous vein versus neovascularization and incompetent groin tributaries. Neovascularization was detected in 1/40 (2%) of EVLTV group and 3 (7.5%)of RFA group, duplex detected

sepheno-femoral refluxes occuring more frequently after RFA have induce to reduce the indications of this type of treatment modality. Although the frequency of recurrent varicosities 2 yrs after EVLTV and RFA were similar, neovascularization, a predictor of future recurrence was less common following EVLTV.

Table 5: Cost Effectiveness of the procedures:

Mean Costs	RFA	EVLTV	MeanCost Ratio(RFA/EVLTV)
Cost of Operation Theater	400	400	1
Preoperative preparation (color doplar) single limb	200	200	1
cost of consumables (assess catheter/iv canula)	650	650	1
cost of anaesthetics and sclerosants	192.75	192.75	1
cost of fiber	36417.5	27040	1.34
post op care (bandage cost /Valfore dressing)	1003.775	881.88	1.20
Follow up (doplar scan)	480	380	1.26
followup cost (compression stockings)	2240.5	1933	1.15
Total Mean Cost	39364.5	29715.1	1.32
SD	1887.8	1430.2	
t-Statistic 25.76 Significance level P< 0.0001			

Costs were informed by the review of operative time, the literature review, and manufacturers' list prices. The total cost of a procedure can be estimated by doing sum of the cost of operative time (staff time plus allocated operating room overheads), kit and consumables (amortized value of high- cost capital items, laser fiber, access catheter, anesthetic, and sclerosant), and other costs (preparation time, recovery time, and other equipment cost).

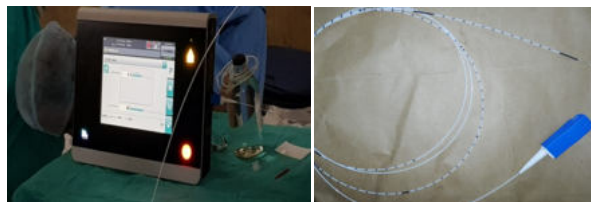


Fig. 1: Duplex USG machine (A) and Laser Fiber (B):



Fig. 2: Intra-operative ultrasound guided venous puncture done with 18 gauge Gelco and guide wire is inserted through it.



Fig. 3: Preoperative image clinical CEAP classification C2



Fig. 4: Postoperative image clinical CEAP classification C2 after EVL

RESULTS

This study focused on comparative study between EVLT and RFA for treatment of varicose veins and cost effectiveness of various techniques. Preoperative grading of the varicose venous disease according to CEAP grading is essential for postoperative assessment and follow up of the disease. For evaluation of junctional reflux and mapping of superficial venous system Preoperative ultrasound & Doppler are essential.

Overall 41-50 yrs was the age group affected most (47.5%) Males were more commonly affected (81.25%) then female prevalence (18.75%). Dilated veins (91.25%) was the most common complaint the majority with most prevalent risk factor was prolonged standing (66.25%) followed by obesity (17.5%) where more no. of patients had combined segments involvement followed by GSV involvement (56.12%) and Left limb involvement was most prevalent (65.00%).

Comparing the significance between different types of surgeries with EVLT, EVLT is significant at $p < 0.05$. It means EVLT is significant in comparison to RFA. In our study recurrence rate was with EVLT (5.00%) and with RFA (22.5%).

The present study includes more number of males (81.25% in EVLT ,86% in RFA) than females (18.75% in EVLT ,14% in RFA). In both the group most of the patients belonged to the age 41-50 years. In our study maximum no. of patient belonged to grade C2-C4 (96% in EVLT, 90% in RFA), all the limbs in both the group were having superficial vein varicosities (grade As). In our study the recurrence rate was with EVLT (5.00%) and with RFA (22.5%).

Hospital stay was nearly the same with EVLT and RFA. EVLT shows Reflux elimination in 96.87% case and RFA in 76.66% cases. Occlusion rate was significantly increased within 1yrs in EVLT (96.87%) while in RFA there is no significant improvement noted. The Mean Cost Ratio in EVLT and RFA found 1.32 (t-Statistic 25.76, Significance level $P < 0.0001$) suggesting EVLT a cost effective procedure over RFA.

DISCUSSION

Total of 80 cases were included in present study and informed written consent was obtained from all the cases. Patients from 18 years to 70 years were taken. Varicose diseases were most common during the 41-50 and 18-30 age group accounting for 47.5% and 20% of cases in the study. Males are affected more (81.25%) than females (18.75%) A Similar study was estimated that 41% of all women will suffer from abnormal leg veins by the time they are in fifties. The general view is that men are affected to the lesser extent by this condition. However the recent **Edinburgh** vein study shows that 40% of man examined had varicose veins (compared with 32% of women). Past studies was similar to our studies the overall complications are less with EVLT compared to RFA. During the past decade, increased interest in venous disorders and the development of new noninvasive diagnostic test and minimally invasive treatment options have led to tremendous advancement in the understanding and management of varicose vein as stated by **Min RJ et al.** (2001). Major risks of Sclerotherapy of saphenous veins include anaphylaxis and intra arterial injection although the risk of latter complication may be reduced with transcatheter technique as stated by **Parsi K et al., Min RJ et al.** Percutaneous methods for treating incompetent GSV are not new. Duplex guided sclerotherapy for treatment of GSV reflux has been attempted, but long term studies have failed to prove durability comparable to surgery as stated by **Bishop CC et al, Cornu – Thenard A, et al, Kanter A, (1998).** **Agus GB et al** (2006) stated that the first important Italian experience with EVL based on preoperative, perioperative and postoperative duplex control and which is also based on the satisfaction of the patient at mid-term or long-term has indicated number of advantages over the standard treatment as stripping method. In terms of reduced postoperative pain, shorter sick leave, a faster resumption of the normal activities, and, in particular, the total absence of DVT, we can conclude that EVL is a good solution for all patients with anatomic and hemodynamic patterns for saphenous vein surgery. A more modern technique of the use of RF energy (VNUS) to eliminate saphenous vein reflux has been developed. In our study recurrence rate was with EVLT (5.00%) which lesser then recurrence with RFA (12.5%). Similar to past studies was showed **Luiz MAV et al (2006)** reported that varicose vein treatment with endovenous laser technique was successful in occluding great saphenous vein and its branches, with self limited adverse effects and recurrence rate lower than 8^h in the follow up period. **Kalteis M et al (2008)** demonstrated that several postoperative symptoms favored EVLA, but the only

significant differences were seen in the minor side effects of surgery at 1 and 4 weeks and paresthesia at the ankle in the first postoperative 7 days. EVLA was associated with a longer period of time until return to work (median [quartiles]) of 20 (14-25.5) days vs 14 (12.8-25) days ($P = .054$). They concluded that endovenous laser ablation combined with high ligation is safe and effective. In our study complications after EVLA and RFA were hyperemia at 17.5% and 35.0%, ecchymosis at 22.5% and 45% and edema at 10.00% and 27.5.0%, respectively. The rate of recanalization was 7.5% in the RFA group. No recanalization was observed in EVLA group. The level of patients satisfied with EVLA was 51.7%, compared to 31.0% for RFA, while 17.2% of patients were satisfied with both procedures. Times to return to daily activity were 1 days in the EVLA group and 1.3 days in the RFA group. Similar to past studies was showed **Mundy L, et al** (2005) concluded that Thirteen studies met the inclusion criteria. Self-limiting features, such as pain, ecchymosis, induration and phlebitis, were commonly encountered after treatment. Deep vein thrombosis and incorrect placement of the laser in vessels were uncommon adverse events. No study has yet assessed the effectiveness of laser therapy in comparison to saphenofemoral junction ligation with saphenous vein stripping. Occlusion of the saphenous vein and abolition of venous reflux occurred in 87.9-100 per cent of limbs, with low rates of re-treatment and recanalization. From the low-level evidence available it seems that EVLT benefits most patients in the short term, but rates of recanalization, re-treatment, occlusion and reflux may alter with longer follow-up. Cost-effectiveness of different treatment modalities in our study maximum cost was for combined therapy. Similar to past studies was showed **Rautio T et al (2002)** reported that endovenous obliteration may offer advantages over the conventional stripping operation in terms of reduced postoperative pain, shorter sick leaves, and faster return to normal activities, and it appears to be cost-saving for society, especially among employed patients. Because the procedure is also associated with shorter convalescence, this new method may potentially replace conventional varicose vein surgery. **Huang Y (2005)** concluded -that EVLT is a novel minimally invasive treatment with advantages of safety, effectiveness and simplicity and it leaves no scars. Its indication can be extended by combining surgical strategies. **Luiz MAV et al** (2006) reported that varicose vein treatment with endovenous laser technique was successful in occluding great saphenous vein and its branches, with self limited adverse effects and recurrence rate lower than 8^h in the follow up period. This study also estimated the cost-effectiveness of EVLT versus RFA for the treatment of varicose veins. The main finding was that EVLT is the most effective and less costly treatment option. Venous diseases are very costly for health services to treat and, by preventing recurrence.

CONCLUSIONS:

In terms of reduced postoperative pain, shorter sick leave, a faster resumption of the normal activities, and in particular, the total absence of DVT, we can conclude that EVLT is a good solution for all patients with anatomic and haemodynamic patterns for saphenous vein surgery. Treating full length of GSV is associated with less residual symptoms. Also small basic modifications in instrumentation can make big differences in the cost of the therapy. EVLT has a better success rate in comparison to RFA and more efficient mode of treatment because of higher elimination of junctional reflux, higher occlusion & ulcer healing rate. The technical success is more with laser ablation in as laser ablation shows highly significant improvement at short term as well as on long term follow-up

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