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RFA vs EVLT: A Comparison of Treatment Options for Varicose Veins

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Abstract
Introduction: *Varicose veins represent a common health problem, the effects of which in terms of disability and health care costs are considerable. Conventional surgical stripping may cause many complications, longer recovery time and higher recurrence rate. The development of new minimally invasive techniques which include Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) are less invasive, may have fewer adverse effects and better cosmetic outcome, causing less impairment of patient's physical or professional activities, with improved quality of life.*
Aims and Objectives: *To compare the technical success, safety and efficacy of RFA and EVLT on follow up of 1 year in symptomatic varicose veins patients*
Material and Methods: *This combined prospective & retrospective study of 200 patients of varicose veins treated with Biolitec laser machine and Celon Lab Power Radiofrequency generator unit with bipolar applicator with the help of Philips IU 22, Doppler and ultrasound machine with linear array 7.5-10 MHz transducer, was carried out at between November 2011 to November 2013.*
Results and Conclusions: *Technical success is more with EVLT in comparison to RFA. EVLT is more efficient mode of treatment due to higher elimination of junctional reflux, higher occlusion & ulcer healing rates. Thus EVLT is an acceptable and efficacious endovenous treatment option over RFA in management of symptomatic varicose veins patients.*
Keywords: *RFA: Radiofrequency Ablation, EVLT: Endovenous Laser Ablation.*

Introduction

"Varicosity is the penalty for verticality against gravity". Varicose veins represent a common health problem, the effects of which in terms of disability and health care costs are considerable. Varicose veins are caused by underlying chronic venous insufficiency with ensuing venous hypertension which leads to a broad spectrum of clinical manifestations, ranging from symptoms like cramps, itching, swelling and leg tiredness to cutaneous findings like varicose veins, reticular veins, telangiectasias, edema, skin pigmentation and ulcerations. Successful long-term results in the treatment of primary varicose leg veins of

truncal origin depend on the elimination of the highest point of reflux and the elimination of the incompetent venous segment. The gold standard for surgical treatment of varicose veins, owing to sapheno-femoral junction (SFJ) insufficiency, together with great saphenous vein (GSV) reflux, is the high ligation and stripping of the GSV often performed under general or spinal anaesthesia.[1,2] Conventional stripping may cause great bruising, postoperative pain, the risks associated with anaesthesia, paresthesia owing to saphenous nerve injury, hematoma and wound infection and lengthen the recovery time of the usual activities.[3] The development of more suitable and flexible instruments and the search for new minimally invasive techniques, with acceptable results in the short and long term, allowed new kinds of treatments,[4] which included Endovenous laser therapy (EVLT), radiofrequency ablation (RFA). RFA produces direct heating of the vein wall, which leads to collagen denaturation, and acute vein constriction.[6] EVLT is a new method for treating large-caliber varicose veins by applying endovenous laser energy (diodes and Neodymium-doped yttrium aluminium garnet (Nd: YAG)) transmitted through an optic fiber.[7] are used for endovenous laser therapy (EVLT)]. It involves percutaneous introduction of a laser fibre into the incompetent vein to produce a non-thrombotic occlusion and acute inflammation of the targeted vein [8,9] . EVLT and RFA are minimally invasive methods of treating refluxing varicose veins; they may be done in an outpatient setting using local anesthesia. These methods, being less invasive than surgical stripping, may have fewer adverse effects and better cosmetic outcome, causing less impairment of patient's physical or professional activities, with improved quality of life.

Aims and Objectives

To compare the technical success (in terms of improvement in clinical CEAP grading) and safety (in terms of post-ablation complications) and efficacy (in terms of venous occlusion rate and ulcer healing rate) of RFA and EVLT on follow up of 1 year in symptomatic varicose veins patients.

Material and Methods

This combined prospective & retrospective study of 200 patients of varicose veins treated with Biolitec laser machine and Celon Lab Power Radiofrequency generator unit with bipolar applicator with the help of Philips IU 22, Doppler and ultrasound machine with linear array 7.5-10 MHz transducer, was carried out at between November 2011 to November 2013. Post operative follow up evaluation was done at 1 month, 6 months and 12 months thereafter patient is asked to follow up. The Clinical photograph of the operated limb was taken, improvement in CEAP grading was documented, follow up colour doppler was done and reflux at SFJ or SPJ, occlusion of the ablated vein were recorded. In patients with venous ulcers, the approximate area of the healing / non healing ulcer was recorded. Statistical analysis as continuous variable (age, pre-operative clinical CEAP and improvement of ulcer healing) were presented as Mean SD. Categorical variable (site of limb, treated veins, and Clinical, Etiopathological, Anatomical, Pathophysiological, (CEAP) grading) were expressed in actual numbers and percentages. Improvement of ulcer healing at different time points were compared by performing Repeated measure ANOVA. Post hoc multiple comparisons were made by Tukey test. Number of limbs with elimination of SFJ/SPJ reflux and number of limbs with complete occlusion of treated veins were compared at different time point in LASER and RFA by performing Kruskal-Wallis oneway ANOVA. Improvement in clinical CEAP at 1, 6 and 12 months compared between LASER and RFA by performing Wilcoxon Rank sum test. Categorical variables were compared by Chi-square test. $P<0.05$ was considered as statistically significant. Statistical software STATA version 10.0 was used for statistical analysis.

Results

Table No-1 Age and Gender distribution of patients

Age in years	EVLT			RFA		
	Male	Female	Total	Male	Female	Total
0-10	0	0	0	0	0	0
11-20	1	0	1	2	0	2
21-30	12	2	14	15	3	18
31-40	26	6	32	26	3	29
41-50	22	5	27	21	4	25
51-60	16	3	19	20	2	22
61-70	6	0	6	4	0	4
>71	1	0	1	0	0	0
Total	84	16	100	88	12	100
Percentage	84%	16%		88%	12%	

Table no 2 Side of limb treated

Side of limb treated	No of limbs			
	LA N=108	%	RFA N=106	%
Right	48	44.4%	52	49.1%
Left	60	55.6%	54	50.9%

Table no: 3 Preoperative clinical CEAP grading

Clinical CEAP grading	No of limbs			
	LA N= 108	%	RFA N =106	%
C1	0	0	0	0
C2	25	23.14	16	15.09
C3	32	29.62	36	33.96
C4	26	22.22	28	26.41
C5	9	8.33	8	7.54
C6	16	14.81	18	16.98
Mean grade	C3.68±1.32		C3.77±1.28	

[**C0** no visible or palpable signs of venous disease, **C1** telangiectasia or reticular veins , **C2** varicose veins , **C3** edema , **C4** skin changes due to venous disorders (pigmentation, eczema, dermatosclerosis), **C5** as **C4** but with healed ulcers , **C6** skin changes with active ulcers]

Table no: - 4 Follow up ultrasound and Doppler evaluation

Month of follow up	No of limbs with elimination of SFJ/SPJ reflux				p-value	No of limbs with complete occlusion of treated veins				p-value
	LA	%	RFA	%		LA	%	RFA	%	
1 Month	100/102	98.04%	94/100	94.0%	0.141, NS	95/102	93.14%	90/100	90%	0.422,NS
6 months	98/98	100%	90/94	95.74%	0.056, NS	92/98	93.87%	84/94	89.36%	0.258,NS
12 months	92/92	100%	88/92	95.65%	0.121, NS	90/92	97.82%	84/92	91.30%	0.010, S
F-value	2.02	-	0.198	-		3.921	-	2.022	-	
p-value	0.135, NS	-	0.820, NS	-		0.022, S	-	0.135, NS	-	

Table no 5 Follow up of patients with healed ulcers

Preoperative area of ulcer	No of limbs affected treated by		1 month		6 months		12 months	
	LA	RFA	LA	RFA	LA	RFA	LA	RAF
>5 cm^2	6	7	0	0	4	3	4	3
<5 cm^2	10	11	8	7	10	8	10	8
Total	16	18	8 (50%)	7 (38.89%)	14 (87.5%)	11 (61.11%)	14 (87.5%)	11 (61.11%)

Table No 6 Comparison of improvement of ulcer healing at different follow-up time in Laser and RFA. (Repeated Measures ANOVA test)

Technique	Factor	F-value	p-value
Laser	Time	18.350	<0.001, HS
	Size*Time	11.057	<0.001, HS
RFA	Time	14.58	<0.001, HS
	Size*Time	3.833	0.015, S

Table No 7 Comparison of Improvement in Clinical CEAP at different follow-up time in Laser and RFA technique. (Post hoc comparison by Tukey' test)

Time	Laser		RFA	
	Mean	p-value	Mean	p-value
Pre	3.68 ±1.32		3.77 ±1.28	
1 month	2.21± 1.63	<0.001, HS	2.58± 1.73	<0.001, HS
6 month	1.48 ±1.31	<0.001, HS	2.05 ±1.65	<0.001, HS
12 month	1.05± 1.24	<0.001, HS	1.70 ±1.73	<0.001, HS

Table No 8 Comparison of Improvement in Clinical CEAP at 1 month , 6 month and 12 month between Laser and RFA technique. (Between Laser and RFA comparison by Wilcoxon rank sum test

Follow-up time	Laser	RFA	p-value
1 month	1.47± 0.84	1.25± 0.89	0.0827, NS
6 month	2.27± 0.97	1.92± 1.02	0.0023, HS
12month	1.21± 1.05	0.92± 0.91	0.0463, S

Table no: 9 Percentage of postoperative complications

COMPLICATIONS	No of limbs			
	LA N=108	%	RF N=106	%
Superficial vein phlebitis	4	3.70%	7	6.60%
Induration	9	8.33%	8	7.54%
Excessive pain and bruising	20	18.51%	16	15.09%
Hematoma	5	4.62%	9	8.49%
Burns	11	10.18%	4	3.77%
Puncture site infection	5	4.62%	11	10.3%
Paresthesia	6	5.55%	5	4.71%
Pulmonary embolism	0	0%	1	0.94%
DVT/ Saphenous thrombus extension	1	0.92%	3	2.83%

Fig I. Biolitec Laser machine with Optical power 15W

Fig II. Biolitec Laser Fibre wavelength 1365 nm with sheath

Fig III. Radiofrequency generator unit (Celon Lab POWER)

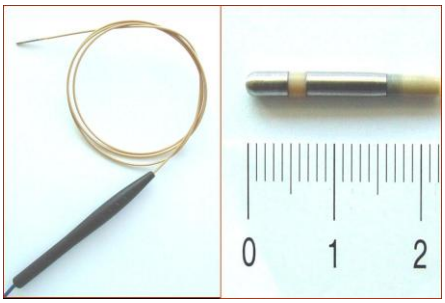

Figure IV: Bipolar RFITT applicator, Dia: 2 mm, Flexible shaft: 115 cm, Active length: 15 mm

Fig V. A 7 cm long 4F sheath is placed in the GSV; through which terumo guide wire is introduced

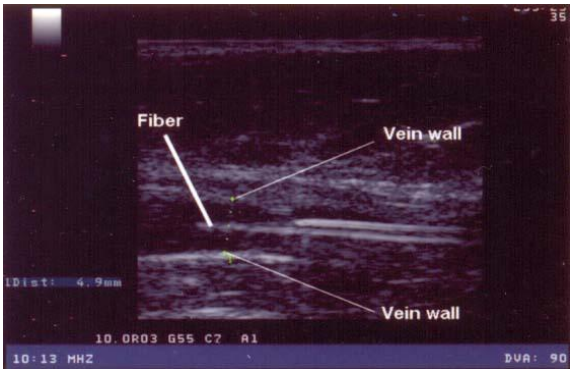

Fig VI. Intraoperative ultrasound guided venous puncture done with 18 gauze Gelco and guide wire is inserted through it

Fig. VII. The sheath and RFA probe are being steadily withdrawn at approximately 0.5 cm per second, such that the acoustic signal is maintained at a constant frequency and pitch

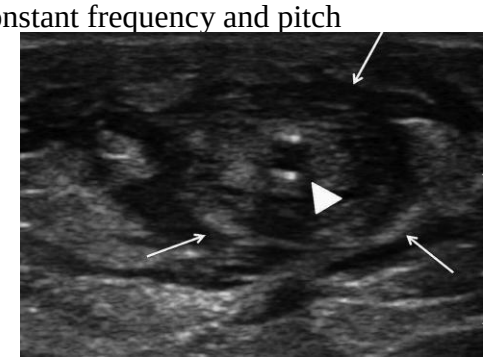

Fig.VIII. Transverse USG shows perivenous tumescent fluid (arrows) around the sheath in the long saphenous vein (arrowhead)

Fig IX. Preoperative CEAP Classification: C4EpAsPr

Fig X. 6 month postoperative clinical CEAP classification C0 after EVLT

Fig XI. Preoperative CEAP grade C6EpAsPr

Postoperative 1 month clinical CEAP classification C5 after RFA

Postoperative 6 month clinical CEAP classification C2 after RFA

Discussion

In our study we have used 1465nm diode laser which is a novel wavelength used so far and a radiofrequency generator unit (Celon Lab POWER, Celon AG Medical Instruments, Teltow, Germany). F Pannier (2009)[10] treated 134 saphenous veins (108GSV, 26 SSV) in 117 legs of 100 consecutive patients. These were treated by 1470nm diode laser and postoperative evaluation was done for 6-12 months in each patient. Proebstle TM, Alm J, et al (2011) [11] in their prospective multicenter trial monitored 295 Radiofrequecy segmental thermal ablation (RSTA) treated GSVs for 36 months. A total of 256 out of 295 treated GSVs (86.4%) were available for 36 months of follow-up. Gale SS, Lee JN, (2010) [12] in their study evaluated 118 patients (141 limbs): 46 (39%) were randomized to RFA and 48 (40%) to EVL and compared early and 1 year results.

In our study 120 veins (108 limbs) of 100patients were treated with LA and 115 veins (106 limbs) of 100 patients treated with RFA and postoperative follow up for 12 months done. The present study included more number of male patients, 84% in LA & 88% in RFA as compared to females, 16% in LA & 12% in RFA. Median age was 42.54± 11.62, range 20-71 years in LA and 41.61 ± 11.65, range 16-67 in RFA. In both groups maximum no of patients belonged to age group of 31-50 years. Most of the past studies conducted in developed countries show female preponderance. This gender distribution is reversed in our study, as in developing countries like India, where the population of working women is less.

Merchant RF, Pichot O et al[13] preoperatively reviewed maximum patients of grade C2 and minimum of grade C6. In our study maximum number of patients (29.6% in LA & 33.9% in RFA) belonged to grade C3. We had significant number of patients (14.8% in LA & 16.9% in RFA) belonging to grade C6. In our study most of limbs (94.44% in LA & 100 % in RFA) had primary varicose veins.

In our study, all the limbs in both groups were having superficial vein varicosities (grade As). None of the patients had deep vein incompetence. 22 out of 108 limbs (22.37%) in LA & 18 out of 106 (16.98) limbs in RFA showed perforator incompetence (grade Ap). In the study done by T. M. Proebstle et al[14], all the patients were having superficial vein incompetence and 48% patients had perforator incompetence. Deep vein incompetence was seen in studies done by F Pannier[10] and T. M. Proebstle et al[14] involving 2% and 6% patients respectively.

Repeated Measure ANOVA test showed that in both techniques over follow –up period, there is no significant increase in reflux elimination rate, also in comparison with RFA, LA does not shows statistically significant improvement but in terms of percentage LA shows reflux elimination in 100% case and RFA in 95.65% cases. Occlusion rate was significantly increased after 6 months in LA (0.022, Significant) while in RFA there is no significant improvement noted. In comparison to RFA, LA shows significant improvement in occlusion rate (p=0.010, significant) at 12 months. Merchant RF, Pichot O et al [13] In their study found that vein occlusion rates were 96.8%, 89.2% % 87.1% and reflux free rates were 96.6%, 91.3% & 88.2% at 1 week, 6 months & 12 month follows up.

Comparing improvement of ulcer healing in terms of follow up at different time and size & time in RFA and LA with repeated measures ANOVA test, both techniques shows highly significant improvement with time (p<0.001).While In terms of size and time, LA ablation shows highly significant improvement (p<0.001) and RFA shows borderline significant improvement. Comparing both techniques in terms of size & time LA shows significant improvement (p=0.011) than RFA. Luiz Marcelo Aiello Viarengo, Joao Poterio-Filho et al [15] obtained very similar results in their study group of 27 patients. Ulcer closure occurred in 3 months in 62.9% (17 limbs) and in 30 days (44.4%) in 12 cases. Ulcer areas smaller than 5 cm^2 had the best response in 90 days. *Ying Huang et al* [32] studied two hundred thirty venous insufficient lower limbs and found that Gaiter ulcerations in all the 9 patients were healed in 2 to 5 weeks after the procedure.

Comparing the improvement in Clinical CEAP at 1 month , 6 month and 12 month between Laser and RFA technique with Wilcoxon rank sum test reveals no significant difference at 1 month (p=0.827). There is highly significant improve-ment at 6 month (p=0.0023) and significant improvement (p= 0.0463) at 12 month in LA in comparison to RFA.

In a comparative study conducted by angiodynamics in 2006 between EVLT and RFA they found that major complications DVT or Saphenous thrombus extension was less with EVLT (0.3%) as compared to RAF (2.1%). Pulmonary embolism was reported in 17 cases in RFA while no case reported with EVLT.

Conclusions

Preoperative baseline categorization of the varicose venous disease according to CEAP grading is essential for postoperative assessment and follow up of the disease.

Preoperative ultrasound & Doppler plays essential role in evaluation of junctional reflux and mapping of superficial venous system.

Technical success is more with laser ablation in comparison to radiofrequency ablation, as laser ablation shows highly significant improvement in clinical CEAP grading at short as well as on long term follow up.

Laser ablation is more efficient mode of treatment in comparison to radiofrequency ablation due to higher elimination of junctional reflux, occlusion & ulcer healing rates.

Most of the adverse effects of both endovascular techniques were transient and self limiting. Minor complications such as pain, bruising and indurations were more frequently encountered in EVLT than RFA, while other minor complications such as thrombophlebitis, hematoma, puncture site infection and major complications such as DVT were more in RFA than LA, thus EVLT is safer than RFA in terms of complications.

Thus laser ablation is an acceptable and efficacious endovenous treatment over radiofrequency ablation in management of symptomatic varicose veins patients.

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